

## Environmental Assessment

1. **Date:** March 29, 2004
2. **Name of Applicant/Notifier:** EMS-Chemie AG/EMS-Chemie (North America) Inc.
3. **Address:** Business Unit EMS-Grivory  
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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), 1,3-benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid, 1,6-hexanediamine and 4,4'-methylenebis[2-methylcyclohexanamine], for use as a non-food-contact layer up to 25  $\mu\text{m}$  in thickness of coextruded multilayer films for packaging all food types under Conditions of Use B through H, as described in Table 2 of 21 C.F.R. § 176.170(c). The FCS will be separated from food by one or more polymeric layers permitted for this use that have a total thickness no less than 8  $\mu\text{m}$ .

The subject polymer offers several technical properties that make it useful in a variety of food, pharmaceutical, and medical device applications. In particular, the polymer provides dimensional stability at high temperatures and gives the film dimensional stability during sealing operations.

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The Notifier does not intend to produce finished food packaging materials from the subject polymer. Rather, the polymer will be sold to manufacturers engaged in the production of food-contact materials. 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 will occur nationwide, with about 76% of the materials 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 subject polymer.

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

The FCS that is the subject of this Notification is 1,3-benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid, 1,6-hexanediamine and 4,4'-methylenebis[2-methylcyclohexanamine]. The Chemical Abstract Service (CAS) Registry No. for the polymer is 112754-95-7.

**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 the subject polymer. Consequently,

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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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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 packaging materials. In these applications, the polymer is expected largely to be used in film form, 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 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. The subject polymer consists of carbon, hydrogen, oxygen, and nitrogen. Thus, no toxic combustion products are expected as a result of the proper incineration of the polymer.

Only extremely small amounts, if any, of the polymer's 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 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 substance is a high

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molecular weight polymer that contains 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 effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the subject polymer. 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 the polymer.

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

### **(b) Water**

No significant effects on the concentrations of and exposures to any substances in freshwater, 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.

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<sup>2</sup> This expectation is confirmed by the results of extraction studies described in Attachment 8 of the FCN. As shown there, when multilayer films were extracted with 10% ethanol or 95% ethanol at 100°C for 2 hours followed by 40°C for 10 days, there were no detectable levels of either the polymer or the monomers from which the polymer is manufactured using analytical methods with a detection limit of parts per billion (ppb). Thus, the quantity of the subject polymer in solid waste deposited in landfills will be extremely small.

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(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 polymer. In particular, the extremely low levels of maximum migration of components of the polymer, demonstrated by the extraction studies, indicate that virtually no leaching of this substance may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. Furthermore, the very low production of the polymer for use in food-contact applications, as indicated in Attachment 12 of this Notification, precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the subject polymer as a result of its proposed use.

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 the subject polymer, 1,3-benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid, 1,6-hexanediamine and 4,4'-methylenebis[2-methylcyclohexanamine], 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. The low levels expected in the human diet from the proposed use of the subject polymer may be considered safe even in the absence of toxicology data.

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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 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 the subject polymer involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject polymer 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 polymer is intended to be used in packaging which will be used in place of similar materials now on the market for use as food packaging. Specifically, the polymer provides dimensional stability at high temperatures and gives the film dimensional stability during sealing operations. Polymers currently used in such applications include other nylon resins that are currently permitted for this use.

The partial replacement of these types of materials by the subject polymer 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, the film applications that are 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 landfill and incineration; the subject polymer will not be used to fabricate bottles, which are the types of containers that are recovered for recycling to a significant extent. Packaging materials produced

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from the subject polymer are expected to be disposed according to the same patterns when it is used in place of 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; the insignificant impact on environmental concentrations of combustion products of the polymer; and the close similarity of the subject polymer to the materials it is intended to replace. 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 excellent qualities of the subject polymer 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 its use, the establishment of an effective FCN to permit the use of the subject polymer as described herein is environmentally safe in every respect.

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**12. List of Preparers**

Lester Borodinsky, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite  
500 West, Washington, DC 20001

**13. Certification**

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

Date: March 29, 2004



Ralph A. Simmons  
Counsel for EMS-Chemie AG/EMS-Chemie (North  
America) Inc.

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