# Environmental Assessment

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| 1. | **Date:** | March 19, 2007 |
| 2. | **Name of Applicant/Notifier:** | EMS-CHEMIE AG/EMS-CHEMIE (North America) Inc. |
| 3. | **Address:** | Reichenauerstrasse<br>CH-7013 Domat/Ems<br>Switzerland<br><br>All communications on this matter are to be sent in care of Counsel for Notifier:<br>Joan Sylvain Baughan, Partner<br>Keller and Heckman LLP<br>1001 G Street, NW, Suite 500 West<br>Washington, DC 20001<br>Telephone: 202-434-4147<br>Facsimile: 202-434-4646 |

**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 1,3-benzenedimethanamine and hexanedioic acid, for use as non-food-contact layers (up to 85 μm in thickness) of multilayer containers for packaging all food types under all conditions of use, as described in Tables 1 and 2 of 21 C.F.R. § 176.170(c). The FCS will be sandwiched between polyethylene terephthalate (PET) layers. In particular, the FCS will be separated from food by one or more layers of PET that are permitted for this use; the PET layer(s) located between the FCS layer and the food will have a total thickness no less than 85 μm. Thus, the subject polymer will be used as a component of PET multilayer bottles. PET bottles typically will contain no more than 5% of the FCS, although there may be PET bottles that may contain slightly more than 5% of the FCS. The PET multilayer bottles containing the FCS will range in size from 0.2 liter to 2 liters maximum. The bottles and rigid containers are expected to package various types of beverages and possibly food, such as condiments. Additional information on the anticipated markets and typical bottle structures is provided in a confidential attachment in the Notification.

The subject polymer offers several technical properties that make it useful in a variety of food, pharmaceutical, and medical device packaging applications. In particular, the polymer is an excellent oxygen and carbon dioxide barrier at both low and high relative humidity conditions, and is a very good water vapor barrier.

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; according to the U.S. Environmental Protection Agency's (EPA) 2005 update regarding municipal solid waste in the United States, 54.3% of municipal solid waste generally was land disposed, 13.6% was combusted, and 32.1% was recovered for recycling and composting.[1]

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 1,3-benzenedimethanamine and hexanedioic acid; thus, the FCS is a copolymer of

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1 *Municipal Solid Waste in the United States: 2005 Facts and Figures*, EPA530-R-06-011, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, October 2006.

isophthalic acid, *m*-xylenediamine, and adipic acid. The Chemical Abstracts Service (CAS) Registry No. for the polymer is 28628-75-3.

**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, 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 a non-food-contact layer of containers, 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 (*i.e.*, PET bottles) containing the subject polymer will be primarily by sanitary landfill or incineration; in addition, approximately 20% of PET bottles are recycled.[2] The subject polymer consists of carbon, hydrogen, oxygen, and nitrogen. Based on the elemental composition of the FCS, the nitrogen content in the FCS has been calculated (available in a confidential attachment to the FCN). With

2 According to a September 29, 2005 report in *Packaging Digest*, the National Association for PET Container Resources (NAPCOR) announced that there was a collected "volume" of 1.03 billion pounds of PET post consumer containers in the United States for the year that ended on December 31, 2004, and that this collected poundage amounted to a recycling rate of 21.6%.

regard to carbon, hydrogen, and oxygen, these are elements that are commonly found in municipal solid waste. With regard to nitrogen, this element could potentially form combustion products that could be toxic at levels much higher than could be present from combustion of this FCS. Based on the proposed use of the FCS, the anticipated market volume (available in a confidential attachment to the FCN), and calculations regarding the maximum introduced level of nitrogen containing combustion products (available in a confidential attachment to the FCN), we have concluded that the FCS will make up a very small portion of the total municipal solid waste currently combusted, the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

In light of EPA's regulations governing municipal solid waste landfills, 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. 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 molecular weight polymer that contains only low levels of low molecular weight polymeric components, the portion of the polymer that can potentially be leachable.

## 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 quantities of any substance will be added to these water systems upon the proper incineration of the polymer or upon its disposal in landfills because no environmental introductions were identified under Item 6. Additionally, in general, migration (diffusion) calculations on these food-packaging materials, which are performed to demonstrate the safety of polymeric packaging, indicate only low levels of migration of substances from the package into food. This supports the premise that the FCS is unlikely to leach from the food-package into the landfill leachate. Even if small amounts of the FCS migrate into the landfill leachate, it is unlikely they will migrate out of the landfill because of EPA's 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 (*see* 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.

**(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 low levels of low molecular weight components of the polymer indicate that virtually no leaching of the 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 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 1,3-benzenedimethanamine and hexanedioic acid, 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.

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. The use of the subject polymer in the fabrication of food-contact materials, however, 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 that will be used in place of similar materials now on the market for use as food packaging. Polymers currently used in such applications include other polyamide resins that currently are 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 for the following reasons. 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. Packaging materials containing the FCS are expected to be disposed according to the same patterns when the FCS is used in place of other polyamides currently used. In addition, it is possible that PET bottles containing the FCS could replace certain glass bottles and aluminum cans. Based on the proposed use of the FCS, the anticipated market volume (available in a confidential attachment to the FCN), and calculations regarding the maximum potential replacement of certain glass bottles and aluminum cans (available in a confidential attachment to the FCN), we have concluded that the FCS will make up a very small replacement of the glass bottles and aluminum cans (at or below 1%) and, therefore, the proposed use of the FCS will not significantly impact the use of energy and resources with regard to the potential replacement of glass bottles and aluminum cans.

The subject polymer will be used as a component of PET bottles, which are the types of plastic containers that are recovered for recycling to a significant extent. PET bottles typically will contain no more than 5% of the FCS, although there may be PET bottles that may contain slightly more than 5% of the FCS, and the bottles will range in size from 0.2 liter to 2 liters maximum. The bottles and rigid containers are expected to package various types of beverages and possibly food, such as condiments. Additional information on the anticipated markets and typical bottle structures is provided in a confidential attachment in the Notification.

The impact of a new polymer entering the PET recycling stream is dependent on its relative market penetration, as well as the ability to either separate the new polymer from PET or that the added polymer is compatible with processing of PET. With regard to the separation of polyamides from PET multilayer bottles, it has been noted that more research and development are needed on current recycling methods.[3] With regard to compatibility with the processing of PET, as noted above, typical PET bottles manufactured in the U.S. will contain no more than 5% of the FCS, although there may be PET bottles that may contain slightly more than 5% of the FCS. A recently published article[4] demonstrates that the presence of up to 10% polyamides[5] in PET does not impact the ability to manufacture functional PET bottles.[6]

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3 Kegel, M. and Kosior, E., "Recycling of Multilayer and Barrier Coated PET Containers," Technical Papers Of The Annual Technical Conference- Society Of Plastics Engineers Incorporated, 2001, Conf 59; Vol 3, pages 2715-2717. Copy attached.

4 Hu, Y.S., Prattipati, V., Mehta, S., Schiraldi, D.A., Hiltner, A., and Baer, E., "Improving gas barrier of PET by blending with aromatic polyamides," *Polymer*, **46**, 2685-2698 (2005).

To substantiate the compatibility of the FCS in multilayer bottles with other PET bottles and, thus, the potential environmental impact on post consumer plastics/PET recycling streams, testing was conducted on blends containing 0%, 25%, and 50% polyamide/PET multilayer recycle bottle[7] content mixed with virgin PET monolayer bottles. The test protocol used to assess the potential environmental impact of multilayer polyamide/PET bottles was established by The Association of Post-Consumer Plastic Recyclers (APR). The most critical aspects of these tests focus on the potential impact on the bottle-to-bottle end use applications. Therefore, tests were conducted to assess the impact on these more critical applications. Because this report contains confidential information, it is included as a confidential attachment to this Notification.

In these tests, three critical parameters were chosen to establish a potential impact of the polyamide barrier on bottle-to-bottle applications; namely, color, haze, and intrinsic viscosity (IV). The determination of color is based on measuring the "**Lab**" values based on the Hunter color system. The **L** value is a reflection of the luminosity, the **a** value is a measure of the degree of redness, and the **b** value represents the degree of yellowness of the sample. Of these three parameters, typically the **L** and **b** values are the two most significant. A decrease in the **L** value causes a darkening in the material. An increase in the **b** value causes the material to take on a yellowish to brown color. Therefore, these are the two most critical values in bottle-to-bottle or sheet type applications when evaluating colorless transparent materials. In fiber applications, however, a color shift in the **Lab** values has little impact, as the material is typically dyed to

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5 The polyamides employed in the study were a copolymer of *m*-xylenediamine and adipic acid and a copolymer of isophthalic acid, *m*-xylenediamine, and adipic acid. The relevance of this study is that the FCS is a copolymer of isophthalic acid, *m*-xylenediamine, and adipic acid.

6 The article also demonstrates that the gas barrier properties of PET are improved by the introduction of 5 or 10 weight % of the aromatic polyamides.

7 The multilayer bottles used in the test weighed 20 grams and contained 5.5% of the food-contact substance (FCS). The structure of the test bottles was PET/FCS/PET.

obtain the desired color. The IV can become critical for applications in which higher molecular weight is required, such as in bottle or strapping. If there is an impact on the PET feed stream that decreases the ability of the material to be solid state polymerized (SSP) under normal conditions of time or final IV, then that application potentially may be affected.

To assess worst-case scenarios for the removal of polyamide from the recycle multilayer bottle material, testing was conducted at 0%, 50%, and 100% bale spiking levels. The materials were subjected to processing representing commercial practices. The specific processing included a given set of conditions representing typical PET processing conditions as established by the APR protocol, including washing, drying, extrusion, and solid state polymerization.

The resulting solid-stated polymerized PET pellets were then blended with virgin PET up to a maximum use level of 50%. The critical values then were determined in the resulting material. The findings are as follows:

(1) PET derived from polyamide/PET multilayer bottles in the simulated recycling stream containing up to 50% recycle was within the acceptable limits for color, defined by the APR test protocol.

(2) PET derived from polyamide/PET multilayer bottles in the simulated recycling stream containing up to 50% recycle was within the acceptable limits for haze, defined by the APR test protocol.

(3) PET derived from polyamide/PET multilayer bottles in the simulated recycling stream containing up to 50% recycle was within the acceptable limits for IV, defined by the APR test protocol.



[redacted]

Based on these test results, it was concluded that there would be no significant impact on the current PET recycle feed streams by introduction of the FCS resulting from its use in multilayer PET bottles. Thus, on this basis, we conclude that there will be acceptable compatibility of PET multilayer bottles containing the FCS with the current PET recycle feed stream.

The acceptable compatibility notwithstanding, the principal basis of the conclusion that the proposed use of the FCS will not have a significant impact on the PET recycling stream is that the market volume of the proposed use of the FCS (available in a confidential attachment) is a very small percentage of the total PET recycled (estimated in 2004 to be 4.8 billion pounds). Reports indicate that when nylon MXD-6, a molecule very similar to the FCS, is a small percentage of PET (up to 4% by-weight), the physical properties of PET for the specific tests listed are not significantly affected.[8,9] Additionally, theoretically, a contaminant in the PET recycling stream must reach a certain amount or threshold before it will disrupt the PET recycling stream.[8,10] Current markets for bottles with barriers include beer, flavored alcoholic beverages, 100% juices, specialty waters, and sports drinks.[11,12] Many of these applications have not

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8 Paquette, K. E.; Batarseh, L. I., Supplement to the Environmental Assessment for Premarket Notification FCN No. 000044 (Formerly FAP 0B4204); FDA: 2000.

9 US EPA. Plastic Beer Bottles, US EPA. www.epa.gov/jtr/jtrnet/plassbott.htm.

10 Markarian, J., Trends and new materials in additives for PET bottles, Polymer Additives & Colors. Copy attached.

11 Mitsubishi Gas Chemical Co., I.; Nanocor. Multilayer containers featuring nano-nylon MXD6 barrier layers with superior performance and clarity, Nanocor. http://www.nanocor.com/tech_papers/NOVAPACK03.pdf#search=%22Multilayer%20containers%20featuring%20nano-nylon%20MXD6%20barrier%20layers%20with%20superior%20performance%20and%20clarity%22.

12 Leavesuch, R., Barrier PET Bottles: No Breakthrough in Beer, But Juice & Soda Surge Ahead. Plastics Technology. 2003. Copy attached.

penetrated the market as much as expected due to cost.[11] However, even if they did, the small market volume requested in the approval of this food contact notification is a small percentage of the total PET currently used in food contact applications; in fact, it is much lower than the threshold percentage needed for this FCS to disrupt the PET recycling stream.

Thus, on the basis of the foregoing, we conclude that use of the FCS in PET bottles as described will have no adverse impact on PET recycling programs.

**10. Mitigation Measures**

As shown above, no significant adverse environmental impact is 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 Food-

Contact Notification to permit the use of the subject polymer as described herein is environmentally safe in every respect.

**12. List of Preparers**

Joan Sylvain Baughan, Partner, Keller and Heckman LLP

Lester Borodinsky, Ph.D., Staff Scientist, Keller and Heckman LLP

**13. Certification**

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

Date: 3/19/07

Joan Sylvain Baughan
Counsel for EMS-CHEMIE AG/
EMS-CHEMIE (North America) Inc.

**<u>Attachments</u>**


Kegel, M. and Kosior, E., "Recycling of Multilayer and Barrier Coated PET Containers," Technical Papers Of The Annual Technical Conference- Society Of Plastics Engineers Incorporated, 2001, Conf 59; Vol 3, pages 2715-2717.

Hu, Y.S., Prattipati, V., Mehta, S., Schiraldi, D.A., Hiltner, A., and Baer, E., "Improving gas barrier of PET by blending with aromatic polyamides," *Polymer*, **46**, 2685-2698 (2005).

Markarian, J., Trends and new materials in additives for PET bottles, Polymer Additives & Colors.

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