Environmental Assessment
Gruppo Mossi & Ghisolfi Food Contact Notification

1. **Date:** August 9, 2008

2. **Name of Applicant/Notifier:** Gruppo Mossi & Ghisolfi
M&G Polymers USA LLC

3. **Address:** P.O. Box 590
6951 Ridge Road
Sharon Center, Ohio 44239

4. **Description of the Proposed Action**

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), Hexanedioic acid, polymer with 1,3-benzenedimethanamine (CAS Reg. No. 25718-70-1) for use as a modifier of ethylene phthalate polymers regulated under 21 C.F. R. § 177.1630 and ethylene phthlate polymers that are subject of an effective FCN, at levels not to exceed 8% by weight, optionally in conjunction with up to 0.015 weight percent cobalt neodecanoate (measured as cobalt) of the finished food-contact articles. The clearance established by this Notification would permit the use of the FCS in contact with Food Types I, VI-A, VI-B and VI C (up to 15% alcohol), as set forth in Table I of 21 C.F. R. § 176.170(c), under Conditions of Use C through G, as set forth in Table 2 of C.F.R. § 176.170(c).

The subject polymer offers several technical properties that make it useful as a modifier of polyethylene phthalate polymers for fabricating articles for a variety of food-contact applications – particularly those, such as beer and wine bottles, which demand greater oxygen barrier properties than can be achieved with unmodified polyethylene phthalate polymers.

The Notifier does not intend to produce finished food packaging from the subject polymer or modified polyethylene phthalate polymers (blends). Rather, the blends will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with the blends 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 modified PET articles will occur nationwide, with the material being land disposed, combusted, or recycled. According to the U.S. Environmental Agency's 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.[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 articles prepared from the polymer blends.

[1] Municipal Solid Waste in the United States: 2005 Facts and Figures, EPA 530-R-06-011, U.S. Environmental Protection Agency (5305W), Washington DC, October 2006.

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

The FCS that is the subject of this Notification is "Hexanedioic acid, polymer with 1,3-benzenedimethanamine (CAS Reg. No. 25718-70-1)".

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 blends. Consequently, information on the manufacturing site and complinace 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 to be used in conjunction with PET polymers to fabricate 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 with the subject polymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill, incineration, or recycle.

In light of the Environmental Protection Agency (EPA) regulations governing municipal solid waste landfills, only small amounts, if any, of the polymer constituents (either before or after use as intended) 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 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 substance is a high molecular weight polymer that contains only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.[2]

With regard to combustion, the EPA reports that the amount of municipal solid waste (MSW) generated in the United States in the year 2003 was 236 million tons of which

[2] This expectation is confirmed by the results of extraction studies described elsewhere in the Notification. As shown there, when a representative of the polymer in a container in its finished form was extracted with 10% ethanol at 66°C for 2 hours followed by 40°C for 30 days, only minute amounts of components of the polymer or its oxidation products were found in the extracts. Thus, the quantity of leachate from the polymer in solid waste deposited in landfills will be extremely small.

14% or 33 million tons were combusted.[3] The final containers manufactured with the FCS are composed of carbon, hydrogen, oxygen, sulfur, and nitrogen. Based on the elemental composition of the FCS, the nitrogen and sulfur content has been calculated (available in a confidential attachment to the FCN). With regard to carbon, hydrogen, and oxygen, these are elements commonly found in municipal solid waste. With regard to nitrogen and sulfur, the complete combustion of containers fabricated with the FCS will produce nitrogen oxides and sulfur dioxide. 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 and sulfur-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 emissions of municipal solid waste currently combusted.[4] 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).

[3] U.S. EPA Municipal Solid Waste Generation, Recycling and Disposal in the United States Facts and Figures for 2003, EPA530-F-05-004, 2005.
[4] Lamont, W.H.; Supplement to the Environmental Information for Food Contact Notification 563; FDA; May 24, 2006.

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 subject FCS. The FCS is of high molecular weight and does not volatilize. Oxidation products formed during use as intended are present in very small quantities and, based on migration studies, are tightly held within the polymer matrix, hence will not be released upon the use and disposal of food contact articles manufactured with the FCS.

As indicated in item 6 above, the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted, the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the food-contact substance will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations.

(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 FCS since no environmental introductions were identified under item 6. Additionally, migration studies conducted to demonstrate the safety of the FCS indicate only very 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. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS, 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 FCS. 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 these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the low production volumes of the polymer for use in food-contact applications preclude any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the polymer.

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 polymer 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 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 violation of applicable laws and regulation, 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 in 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 in food packaging. Polymers 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 incorporation into a finished food packaging article 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 bottles containing the FCS could replace certain glass bottles and aluminum cans. Based on the proposed use of the FCS and the anticipated market volume (available in a confidential attachment to the FCN), we have concluded that the FCS will make up a very small replacement of glass bottles and aluminum cans (below 1%). 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 FCS is primarily intended for use as a component of PET bottles for packaging beer and wine that are among the types of plastic containers that are recovered for recycling to a significant extent. The impact on the recycle stream of introducing a bottle containing a new polymer is dependent on its relative market penetration as well as its compatibility with the existing stream or the ability to separate the bottle from the existing stream. With regard to market penetration, the total amount of post-consumer PET purchased for recycling in 2006 was 1.27 billion pounds.[5] The data presented in a confidential attachment to the FCS indicate that bottles containing the FCS represent a very small fraction of the total PET recycle stream.

[5] National Association for PET Container Resources 2006 Report on Post consumer PET Container Recycling Activity, http://www.napcor.com/pdf/2006PET_Report.pdf

With regard to separation, since the intended application of the FCS is for use as a component of beer bottles - typically amber or green bottles - they will be incorporated into an existing alternative recycle stream, i.e., the colored PET recycle stream that currently exists for PET beer bottles and other colored bottles. This stream is currently used predominantly to produce carpet fiber and strapping. In 2006, the amount of PET collected that was used for strapping was approximately 132 million pounds and the amount used for fiber was approximately 422 million pounds.[5] Assuming that the anticipated annual production volume (available in a confidential attachment to the FCN), of bottles manufactured with the FCS that are intended for use in the U.S. is recycled at the same rate as all PET bottles (23.5 %), they would represent a small fraction of the current colored PET stream.

With regard to compatibility, a recently published article demonstrates that the presence of up to 10% polyamides in PET does not impact the ability to manufacture functional PET bottles.[6] As indicated, bottles containing the FCS will be separated as part of the colored PET stream for use in fibers and strapping. However, if, as a result of malfunction of automatic color sortation equipment or manual sortation error, a fraction of bottles containing the FCS inadvertently be included in the PET stream intended for manufacture of clear bottles, the level of the FCS would likely be significantly lower than the 10% level.[7] Another recent report indicated that when Nylon, specifically MXD6, is a small percentage of PET (up to 4% by weight), the physical properties of PET for the

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[6] Hu, Y.S., Prattipati, V. Metha, S., Schiraldi, D.A., Hiltner, A., and Baer, E., "Improving Gas Barrier of PET by Blending with Aromatic Polyamides," Polymer, 46, 2685-2698 (2005).

[7] Separation efficiencies of amber or green bottles containing the FCS will be no different from separation efficiencies of green, blue and amber bottles currently in the recycle stream.

specific tests listed are not significantly affected.[8] Additionally, theoretically, a contaminant in the PET recycling stream must reach a certain amount or threshold before it will disrupt the PET recycling stream. Current markets for bottles with Nylon barriers include beer, flavored alcoholic beverages, 100% juices, specialty waters and sports drinks.[9] Many of these applications have not penetrated the market as much as expected due to cost.[6] However, even if they did, the market volume for the intended market (beer and wine) indicated in this FCN 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 to disrupt the PET recycling stream.

Thus, on the basis of the foregoing, we conclude that the 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 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 insignificant impact on the use of resources and energy when compared with the materials they are intended to replace. Thus, the use of the

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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] 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%barrier%20layers%20with%20superior%20performance%20and%20clarity%22.

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 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 polymer would otherwise replace; such action would have no environmental impact. In view of 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 establishment of an effective Food Contact Notification to permit the use of the subject polymer as described herein is environmentally safe in every respect.

11. List of Preparers

Edward N. Nowak, Senior Staff Regulatory scientist, Gruppo Mossi & Ghisolfi, P.O. Box 590, 6951 Ridge Road, Sharon Center, Ohio 44274

12. Certification

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

Date: Sept 3, 2008

Delane N. Richardson, Director
Research & Development
Gruppo Mossi & Ghisolfi