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ENVIRONMENTAL ASSESSMENT
GRUPPO MOSSI & GHISOLFI FOOD CONTACT NOTIFICATION

1. **Date:** September 30, 2005

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

3. **Address:** P.O. Box 590
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4. **Description of the Proposed Action**

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), 1,3-benzenedicarboxylic acid, 5-sulfo-, monolithium salt (CAS Reg. No. 46728-75-0) for use as a modifier of ethylene phthalate polymers regulated under 21 C.F.R. § 177.1630 and ethylene phthalate polymers that are the subject of an effective FCN, at levels not to exceed 0.6% by weight 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, II, VI-A, VI-B, and VI-C (up to 15% alcohol), as set forth in Table 1 of 21 C.F.R. § 176.170(c)), under Conditions of Use C through G, as set forth in Table 2 of 21 C.F.R. § 176.170(c).

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The subject copolymers offer several technical properties that make them useful as the basic polymer for fabricating articles for a variety of food-contact applications. In essence, the subject copolymers are slightly modified versions of polyethylene terephthalate copolymers currently found in a variety of food-contact applications, and the subject copolymers may be used in the same applications as those currently used.

The Notifier does not intend to produce finished food packaging from the subject copolymers. Rather, the copolymers will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with the copolymers 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 will occur nationwide, with the material being land disposed, combusted, or recycled. According to the U.S. Environmental Protection Agency's 2001 update regarding municipal solid waste in the United States, 55.7% of municipal solid waste generally was land disposed, 14.7% was combusted, and 29.7% 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 copolymers.

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[1] *Characterization of Municipal Solid Waste in the United States: 2001 Update*, EPA 530-R-03-011, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, October 2003.

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, 5-sulfo-, monolithium salt (CAS Reg. No. 46728-75-0)."

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 copolymers. 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 copolymers to fabricate packaging materials. In these applications, the copolymers are expected to be used as the basic polymer to fabricate all forms of 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 by the subject copolymers will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

Only extremely small amounts, if any, of the copolymer 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 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 collections 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.[2]

With regard to combustion, the EPA reports that the amount of municipal solid waste (MSW) generated in the United States in the year 2001 was 229.2 million tons. After materials recovery, the total amount of MSW disposed of in 2001 was 161.2 million tons. Of this amount,

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[2] This expectation is confirmed by the results of extraction studies described elsewhere in the Notification. As shown there, when a representative sample of the copolymer was extracted with 10% ethanol at 66°C for 2 hours followed by 40°C for 30 days, only minute levels of components of the copolymer produced from the FCS were found in the extracts, at a maximum level of 23 parts per billion (ppb). Thus, the quantity of leachate from the copolymers in solid waste deposited in landfills will be extremely small.

33.6 million tons were combusted.[3] The subject copolymers are composed of carbon, hydrogen, oxygen, sulfur and lithium, elements commonly found in municipal solid waste (MSW). The complete combustion of the subject copolymers will produce carbon dioxide, water, sulfur dioxide (a gas that has the potential to cause adverse environmental effects by contributing to acid precipitation), and lithium which will end up in the incineration ash. Because the market volume estimate of the subject copolymers to manufacture food-contact articles is a small fraction of the total MSW generated and disposed of in the United States and because the subject copolymers will replace and compete with similar materials (see Item 9 below), adding to the waste that is combusted will not alter significantly the emissions from municipal waste combustors. Because of the low levels of combustion products compared to the amounts currently generated by municipal waste combustors, we do not expect that the combustion of the subject copolymers will cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, *i.e.*, 40 C.F.R. Part 60.

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 copolymers produced from the FCS. 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 articles manufactured with the copolymers.

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[3] *Municipal Solid Waste in the United States: 2001 Facts and Figures*, EPA530-S-03-001, United States Environmental Protection Agency (5305W), Washington DC, 20460, October 2003.

The products of complete combustion of the copolymer would be carbon dioxide and water, along with small amounts of sulfur dioxide and lithium; 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.

(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 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 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 copolymers. In particular, the extremely low levels of maximum migration of components of the copolymers, 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 very low production of the copolymers for use in food-contact applications precludes any substantial release to the environment of their 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 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 the copolymers in the manufacture of articles intended for use in contact with food.

8. Environmental Effects of Released Substances

No information need be provided on the environmental effects of substances released into the environment as a result of the use and disposal of the subject copolymers in landfills and by combustion, because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment. Therefore, the use and disposal of the subject copolymers in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of the copolymers 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 packaging which will be used in place of similar materials now on the market for use in food packaging applications. Polymers currently used in the applications in which the subject copolymers are anticipated to be used include other polyethylene terephthalate (PET) modifications. As the copolymers produced from the FCS are PET copolyesters that otherwise comply with 21 C.F.R. § 177.1630 or an applicable Food Contact Notification, containing up to a maximum of 0.6 weight percent 1,3-benzenedicarboxylic acid, 5-sulfo-, monolithium salt units, the addition of 0.6% 1,3-benzenedicarboxylic acid, 5-sulfo-, monolithium salt units does not cause a significant change in the physical properties of PET. Information provided in Attachment 2 to the Notifier's September 30, 2005 letter demonstrates that the subject copolymers have the same performance properties as unmodified PET used for manufacturing food-contact articles.

The partial replacement of these types of materials by the copolymers is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymer, and its conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of the other polymers. While the change requested in this FCN involves use of the copolymers in the fabrication of bottles, bottles fabricated from the subject copolymers are virtually identical to bottles manufactured from currently available PET copolymers and therefore, bottles manufactured using the subject copolymers collected in the recycle stream should be compatibly coextruded with bottles manufactured using current PET copolymers. Packaging materials produced from the copolymers are expected to be disposed of according to the same patterns when they are used in

place of the current materials. While PET bottles are the predominant food packaging articles recovered for recycling, the compatibility of the modified PET will not have an 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 copolymers. 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 copolymers, 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 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 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 copolymers would otherwise replace; such action would have no environmental impact. In view of the fact that the copolymer 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 copolymers 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 her knowledge.

Date: 9/30/05

Catherine R. Nielsen
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