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ENVIRONMENTAL ASSESSMENT
WELLMAN, INC. FOOD CONTACT NOTIFICATION

1. **Date:** December 29, 2005

2. **Name of Applicant/Notifier:** Wellman, Inc.

3. **Address:** 1041 521 Corporate Center Drive
Fort Mill, South Carolina 29715

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 a clearance for the food-contact substance (FCS), dimethyl sulfoisophthalate, sodium salt (DMSIP) (CAS Reg. No. 3965-55-7) for use as a modifier in polyethylene terephthalate (PET) polymers regulated under 21 C.F.R. § 177.1630, at levels not to exceed 1 mole percent based on total diacids (diesters), or 0.5 mole percent based on the finished PET. The clearance established by this Notification would permit the use of the FCS in contact with all Food Types, 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).

The modified PET will be used along with MXD6-nylon in the manufacture of carbonated soft drink bottles. The modified PET/nylon blends may also be used in the manufacture of bottles for alcoholic beverages, particularly beer.

The Notifier does not intend to produce finished food packaging from the subject polymer. Rather, the modified PET will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with 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 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 modified PET.

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

The FCS that is the subject of this Notification is "Dimethyl sulfoisophthalate sodium salt (DMSIP) (CAS Reg. No. 3965-5-7)."

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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.

The modified PET which is made with the FCS has a Tg and Tm similar to those of standard PET. Crystallization rate is slightly reduced compared to standard PET grades (but not significantly), and intrinsic viscosity is comparable.

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 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 modified PET to fabricate packaging materials. In these applications, the polymer is expected to be used as the basic polymer 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 or incineration.

Only extremely small amounts, if any, of the polymer 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, 33.6 million tons were combusted.[3] The subject polymer is composed of carbon, hydrogen, oxygen, sulfur and sodium, elements commonly found in municipal solid waste (MSW). The complete combustion of the subject polymer will produce carbon dioxide, water, sulfur dioxide (a gas that has the potential to cause adverse environmental effects by contributing to acid precipitation), and sodium which will end up in the incineration ash. Because the market volume estimate of the subject polymer to manufacture food-contact articles is a small fraction of the

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[2] This expectation is confirmed by the results of extraction studies described on pages 79-80 of the Notification. As shown there, when a representative sample of the copolymer was extracted with n-Heptane at 66°C for 2 hours followed by 49°C in 50% ethanol for 24 hours, only minute levels of components of the polymer produced from the FCS were found in the extracts. Thus, the quantity of leachate from the polymer in solid waste deposited in landfills will be extremely small.

[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.

total MSW generated and disposed of in the United States and because the subject polymer 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 DMSIP-modified PET 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 polymer produced from the FCS. 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 would be carbon dioxide and water, along with small amounts of sulfur dioxide and sodium; 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 fresh water, 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.

(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 these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the relatively low production volumes 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 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. <u>Environmental Effects of Released Substances</u>

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 polymer 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 polymer 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 polymer in which the FCS is incorporated involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the modified PET 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 in food packaging applications. The subject polymer is anticipated to be blended with up to 30% of hexanedioic acid polymer with 1,3 benzenedimethanamine (MXD-6). As the polymer produced from the FCS are polyesters that otherwise comply with 21 C.F.R. § 177.1630, the addition of up to a maximum of 1 mole percent based on total diacids (diesters) or 0.5 mole percent based on the finished PET does not cause a significant change in the physical properties of PET. (See Item 5, above.)

The addition of the DMSIP in the PET is intended to facilitate blending with MXD-6, the use of which as an additive in PET improves the oxygen barrier properties of the finished resin, allowing it to be used to package low-alcohol foods, such as beer and carbonated soft drinks (CSD).[4] In this regard, Nylon MXD-6 can be more easily dispersed in PET that is modified with the FCS. This improved dispersity enhances the appearance of the PET/nylon blend by reducing haze; however, it does not improve the oxygen barrier properties of PET (the characteristic that otherwise limits the utility of PET for use in the production of beer bottles and similar

[4] Because of the cost of the modified polymer and the current technical sufficiency of PET bottles that are larger than 500 ml, the finished blend is not expected to be used in the production of carbonated soft drink bottles that are larger than about 16 ounces.

applications). Accordingly, the ability to bottle beer and other low-alcohol beverages with the DMSIP-modified PET/Nylon blend is made possible, from a technical standpoint, by the presence of Nylon MXD-6, rather than the FCS.

Nonetheless, the presence of the FCS in PET that is blended with Nylon MXD-6 and is used to produce beer bottles will not impact the use of energy and resources, as bottles produced from the FCS are expected to compete with, and to some degree, replace existing PET/Nylon bottles. Although it is possible that bottles produced from the FCS will also replace glass and aluminum beer containers to some limited extent, these PET bottles will be incorporated into an existing, alternative recycle stream, *i.e.*, the colored PET recycle stream that currently exists for PET beer bottles. This stream is currently used predominantly to produce carpet fiber and strapping. As noted in the physical property description presented in Item 5 above, copolymers produced from the FCS have substantially identical properties as unmodified PET. Thus, the use of the FCS to produce PET that will be used in beer bottles will not adversely affect the recycling of such PET.

Likewise, the presence of the FCS in PET that is blended with Nylon MXD-6 and is used to produce CSD bottles will not impact the use of energy and resources, as bottles produced from the FCS are expected to compete with, and to some degree, replace PET/Nylon bottles. Although it is possible that bottles produced from the FCS will also to some limited extent replace aluminum containers and unmodified PET containers, as pointed out above, because this market is practically expected to exclude containers larger than about 500 ml, the amount of materials that may enter the recycle stream will be sufficiently low that articles produced from

the modified PET/nylon blends will process through the current PET recycling systems with no adverse affects to downstream products or processing.[5]

In sum, the partial replacement of these types of materials by the 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 the other polymers. Further, 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 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 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 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

[5] The primary concern with the use of PET/nylon blends in the recycle stream is the tendency of the nylon to yellow through repeated recycling such that the finished bottle will not meet standard quality requirements. If the amounts of nylon added to the stream are limited, as is the case here, this does not become an issue.

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 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

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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: December 29, 2005

George G. Misko
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