

Attachment 7 - Environmental Assessment

1. **Date** June 9, 2003
2. **Name of Applicant/Notifier** E.I. duPont de Nemours and Company
3. **Address** All communications on this matter are to be sent in care of Counsel for Notifier, George G. Misko, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Telephone: 202.434.4170.

4. **Description of the Proposed Action**

The action requested in this Notification is to establish a clearance for 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol for use as components of food-contact articles. The purpose of the Notification is to permit the use of the subject polymer in the manufacture of food-contact articles, except bottles, in contact with all non-alcoholic foods under conditions as severe as Condition of Use C. Examples of food packaging materials that may be made from the food-contact substance include, but are not limited to, long-term shelf-stable food packaging, soup cups, ice cream carton liners, ice cream spoons, microwave food trays, disposable coffee cups, meat trays, case-ready meat packaging, and dairy food packaging.

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The Notifier does not intend to produce finished food packaging materials from the subject polyester. Rather, the copolymer 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 being deposited in land disposal sites, and about 24% combusted.¹

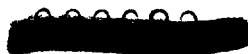
The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the subject polymer.

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

The food-contact substance that is the subject of this Notification is 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol, *i.e.*, a copolyester produced from dimethyl terephthalate, dimethyl glutarate, sodium 5-sulfodimethylisophthalate, and ethylene glycol. The polymer is a polyester derived from diols and diacids or dimethyl esters. Thus, the structure is one in which the polymer backbone consists of alternating units derived

¹ *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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from diols and acids/esters. The Chemical Abstracts Service (CAS) Registry Number for the polymer is 65072-10-8, and its tradename is _____ or _____


Finally, the M_w and M_n for the substance are approximately 45,700 and 15,800, respectively, for a M_w/M_n of approximately 2.89.

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 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol. 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 to be used in food-contact articles, except for bottles, 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 of as part

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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. Disposal by composting in the U.S. is not expected to be significant; furthermore, this polymer is not marketed as biodegradable.

The subject polymer consists of carbon, hydrogen, oxygen, and sulfur. The combustion products are expected to be carbon dioxide and water; sulfur is a small component of the polymer (less than 0.23% by weight) and, therefore, is not expected to give rise to significant levels of sulfur-containing combustion products. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymer.

Only extremely small amounts, if any, of 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol 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

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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.

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 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol. 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 these polymers.

The products of complete combustion of the polymer largely would be carbon dioxide and water; 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.

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(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 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol. In particular, the extremely low levels of maximum migration of components of 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol, 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. Furthermore, the very low production of 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol for use in food-contact applications precludes any substantial release to the

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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 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 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol 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. As discussed in Part III of the Notification, the polymer is expected to be safe when used as intended. Furthermore, none of the monomers used in the manufacture of the polymers are considered to be carcinogens.

Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the polymers. 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.

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9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use, and disposal of 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol 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 copolymer 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, as discussed in Item 4 above, the proposed use in this Notification for the subject polymer is as a component of food-contact articles, except for bottles. Its function in these containers is to serve as the basic container material. Polymers currently used in such applications include, but are not limited to, polyester and polystyrene.

The partial replacement of these types of materials by 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol 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, similar substances to the substance that is 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 sanitary landfill and incineration; bottles, the

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types of containers that are recovered for recycling to a significant extent, are not of interest to the Notifier at this juncture. Packaging materials produced from 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol are expected to be disposed of according to the same patterns when they are used in place of the 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 they are 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

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subject polymer would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol 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 1,3-benzenedicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with dimethyl 1,4-benzenedicarboxylate, dimethyl pentanedioate and 1,2-ethanediol as described herein is environmentally safe in every respect.

12. List of Preparers

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

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

Date: June 9, 2003

[Redacted Signature Box]

George G. Misko
Counsel for E.I. duPont de Nemours and Company

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