ENVIRONMENTAL ASSESSMENT

1. JUNE 2, 2006

2. PTP PLASTIC TECHNOLOGIES & PRODUCTS B.V.

3. 116 EVROPSKA STREET
PRAGUE, PRAHA 6, 16000, CZECH REPUBLIC

4. DESCRIPTION OF THE PROPOSED ACTION

a. Requested Action

It is proposed that poly(ethylene terephthalate), modified with a derivative of hexamethyldisilazane and tetraethyl orthosilicate [redacted] be approved for use as an indirect food additive through the premanufacture process utilizing the FDA Form 3480 "Notification for New Use of a Food Contact Substance." [redacted] is proposed for use as a substitute for virgin PET in food-contact articles as specified under 21 CFR 177.1630 (Polyethylene phthalate polymers). [redacted] is intended to contact all Food Types under the conditions of use for which PET food-contact articles made from virgin PET are approved (Food types I – IX, Conditions of Use D through G). This substance is added at a maximum level of 100% by weight to virgin PET polymers.

b. Need for Action

The use of the FCS as a substitute for virgin PET in food-contact articles has the following desirable, intended technical effects: comparable manufacturing specifications (i.e., the physical or chemical properties) to those for approved food-contact articles made from 100% virgin PET. In addition, the substitution of the FCS will reduce the use of virgin PET in food-contact articles and reduce the amount of PET food-contact articles disposed of in municipal solid waste landfills or combusted.

c. Location of Use/Disposal

The FCS will be incorporated into virgin PET resins that are then used in the production of commercial food-contact containers and films, and remain with the PET food-contact articles through use and disposal. The manufacturing sites of the PET food-contact articles are expected to be widely distributed throughout the United States. Disposal of the PET food-contact articles containing the FCS is expected to occur nationwide with the materials ultimately being recycled, deposited in municipal solid waste landfills, or combusted.

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5. IDENTIFICATION OF THE SUBSTANCE THAT IS THE SUBJECT OF THE PROPOSED ACTION

a. Chemical Name

Poly(ethylene terephthalate), modified with a derivative of hexamethyldisilazane and tetraethyl orthosilicate

b. Common Name(s)

[redacted]

c. Commercial Name

[redacted]

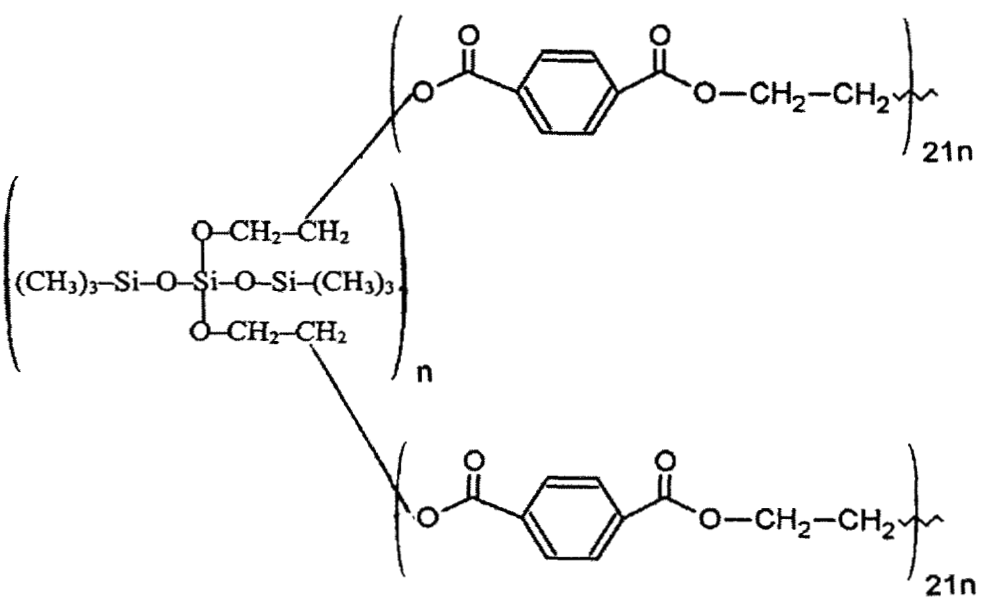
d. CAS Registry Number

882435-29-2

e. Empirical Formula

$(C_{10}H_{26}O_4Si_3)_n(C_{10}H_8O_4)_{42n}$

f. Structural Formula



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g. Properties

Parameter	Units	Value
Glass temperature (Tg)	°C	80
Tm	°C	252
Crystallinity	%	40-65
M_N	Daltons	19,623
M_W	Daltons	51,218
M_W / M_N	Unitless	2.6
Intrinsic Viscosity	dL/g	0.77
Melt flow index	g/10 min	1.8 – 5.0
Tensile Tests:		
Stress at yield	N/mm^2	56.87
Elongation at yield	%	3.80
Stress at break	N/mm^2	45.47
Elongation at break [%]	%	213
E-Modulus [N/mm^2]	N/mm^2	2287

6. Introduction of Substances into the Environment

a. Introduction of substances into the environment as a result of manufacture

To the best of our knowledge, no extraordinary circumstances pertain to the manufacture of the FCS.

b. Introduction of Substances into the Environment as a Result of Use

[redacted] is completely incorporated into food-contact articles and functions in finished containers, and essentially all of it is expected to remain with food-contact articles throughout their use. As such, little or no substances are expected to be introduced into the environment from the use of [redacted] in the manufacture of PET food-contact articles.

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c. Introduction of Substances into the Environment as a Result of Disposal

Because the FCS is intended to compete with and replace other substances already in use in the manufacture of PET food-contact articles (see Format Item 9), disposal of the food-contact articles containing the FCS in landfills or by combustion will not alter levels of potential leachates or emissions compared to PET food-contact articles already disposed of in municipal waste.

Based on the migration studies that were performed to demonstrate the safety of this FCS, we expect only very low levels of substances to leach from the food-contact articles into landfills. Moreover, even if very small amounts of substances migrate from the food-contact articles into landfills, we expect only extremely low quantities to enter the environment. This finding is based on the regulations of the Environmental Protection Agency (EPA), governing municipal solid waste landfills, i.e., 40 CFR Part 258.

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 2000 was 161.2 million tons. Of this amount, 33.6 million tons was combusted.[(1)] The FCS is composed of carbon, oxygen, hydrogen, nitrogen, and silicon elements commonly found in MSW. The complete combustion of the FCS will produce silicon dioxide, carbon dioxide, nitrogen, and water. Although the market volume of the FCS (See Confidential Attachment to the Environmental Assessment) is projected to be a significant percentage of total market volume, the FCS is intended to replace other substances in the production of PET food-contact articles (see Format Item 9). Consequently, adding the food-contact articles containing the FCS to 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 food-contact articles containing the FCS will cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, i.e., EPA's regulations in 40 CFR Parts 60 and 62[(2)] and local government air emission regulations.

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(1) EPA, 2003, *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.

(2) Title 40--Protection Of Environment, Chapter I--Environmental Protection Agency:
Part 60--Standards of Performance for New Stationary Sources;
Part 62--Approval and Promulgation of State Plans for Designated Facilities and Pollutants
Part 258--Criteria for Municipal Solid Waste Landfills.
No copies of these documents are attached or in the FAMF file.

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7. Fate of the Emitted Substance into the Environment

No information need be provided on the fate of substances released into the environment as a result of use and disposal of food-contact articles containing the FCS in landfills and by combustion, because, as discussed under Format Item 6 above, only very small quantities, if any, of substances will be introduced into the environment. Therefore, the use and disposal of the food-contact articles containing the FCS in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 CRF Parts 60 and 258.[(2)]

8. Environmental Effects of the Released Substance

No information need be provided on the environmental effects of substances released into the environment as a result of the use and disposal of food-contact articles containing the FCS in landfills and by combustion, because, as discussed under Format 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 food-contact articles in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 CFR Parts 60 and 258.[(2)]

9. Use of Resources and Energy

Resources and energy utilization to produce or dispose of the FCS or food-contact articles containing the FCS are not expected to be affected by the action. Overall US production of PET food-contact articles is expected to remain essentially unchanged as a consequence of this action because the FCS is intended to compete with and replace other products already in use in the manufacture of these food-contact articles. Consequently, there is essentially no effect on the use of natural resources and energy.

10. Mitigation Measures

Mitigation measures for the proposed action need not be considered because no potentially adverse effects have been identified.

11. Alternatives to the Proposed Action

Alternatives to the proposed action need not be considered because no potential adverse effects have been identified.

12. List of Preparers

Susan D. Phillips, Manager at ENVIRON International Corporation. M.S. in Pharmacology and Toxicology. Consultant in chemical, toxicological, and pharmacological sciences.

13. Certification

The undersigned official certifies that the information presented is true, accurate and complete to the best of the knowledge of PTP Plastic Technologies & Products B.V.

[redacted]

Signature of Responsible Official

5.29.2006

Date

George Dadiani, Chief Operating Officer

Name and Title of Responsible Official (Printed)

14. References

Complete citations for all information referenced in the EA are in footnotes within the EA. There are no copies of these regulatory citations either attached or in FAMF No. 755.

15. Attachments

One confidential attachment is present.

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