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3M CO			
Contractor			
COVANCE LABORATORIES			
Document Title			
INITIAL SUBMISSION: LETTER FROM 3M CO TO USEPA REGARDING REVIEW OF DRAFT REPORT OF 6-MONTH PRIMATE FEEDING STUDY WITH AMMONIUM PERFLUOROCTANOATE, DATED 111999			
Chemical Category			
AMMONIUM PERFLUOROCTANOATE			

A 02

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3M

INITIAL SUB- MISSION



BEH

A 03

Katherine E. Reed, Ph.D.
Executive Director

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November 19, 1999

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Document Processing Center (7407)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
US EPA
401 M Street, SW
Washington, DC 20460

Re: TSCA 8(e) SUBSTANTIAL RISK NOTICE ON:
Ammonium Perfluorooctanoate CAS# 3825-26-1

Dear Sir:

3M has recently completed a review of the draft report on a 6-month primate feeding study performed with ammonium perfluorooctanoate (PFOA) by Covance Laboratories, Madison, Wisconsin. Male cynomolgus monkeys were given daily doses by intragastric capsule deposition of 0 (n=6), 3 (n=4), 10 (n=6) and 30 (n=6) mg/kg ammonium perfluorooctanoate. Significant illness occurred in the 30 mg/kg dose group within several weeks. Dosing was stopped while the animals recovered. Dosing was resumed at 20 mg/kg. At the end of the six month dosing period, two animals in the control, mid and high dose groups were allowed to recover for 90 days. One high dose animal was sacrificed in moribund condition on day 29. This animal suffered hepatic lesions which are felt to be compound-related. Other high dose animals also exhibited liver toxicity.

The following findings are being reported by 3M under TSCA 8(e):

- Significant increased liver-to-body weight ratios were observed in all dose groups. There was no corresponding adverse pathology in the two lowest dose groups (3 mg/kg/day, 10 mg/kg/day) at terminal sacrifice. Liver weight increases were reversed after a 90 day recovery period.
- Preliminary analytical results indicate the serum levels of PFOA for these two lower dose groups are similar to those found among the highest PFOA serum levels observed in a small number of 3M Cottage Grove chemical production employees. Workplace medical surveillance activities have been conducted at 3M since the 1970's. Employees' fluorochemical levels, whether measured as total organic fluorine or as PFOA, have not been associated with clinical hepatic toxicity.

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- In addition, one low dose (3 mg/kg/day) test animal was sacrificed in moribund condition on study day 139. An independent pathology review of this case did not reveal a specific cause of morbidity. The effects observed in this animal were not consistent with the significant hepatotoxicity observed at the high dose and may not be compound-related. There were no effects, other than increased liver weight, in the remaining three animals tested at the low dose

This chemical is produced by 3M and is used by industrial customers as a process aid. 3M has and will continue to conduct medical monitoring of its chemical production workers and to reduce potential for worker exposure.

A copy of the final study report will be sent to the EPA when received.

Please contact Dr. William Weppner, 651-733-6374, for further information.

Sincerely,

Katherine E. Reed

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