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3M

April 20, 2000

Attn: Section 8(e) Coordinator
Document Processing Center (7407)
Office Of Pollution Prevention And Toxics
United States Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Re: **SUPPLEMENT TO TSCA SECTION 8(e) NOTICE ON: N-Ethyl Perfluorooctyl Sulfonamido Ethanol (N-EtFOSE) and Perfluorooctane Sulfonate (PFOS) Docket Numbers: 8EHQ-0998, 373, 374, 394**

Dear Sir or Madam:

On February 15, 2000, 3M submitted final reports for two-generation rat reproduction studies on the above referenced compounds. 3M had originally submitted a TSCA Section 8(e) notice dated September 14, 1998 based on preliminary data from these studies.

With this letter, 3M is supplementing these earlier submissions as follows:

- ⇒ 3M is submitting an amended final report for the two-generation rat reproduction study on PFOS (Sponsor's Study number T-6295.9). This amended final report supercedes our earlier submission. It contains several clarifications, including that there were no toxicologically important effects on pup survival or growth at the 0.4 .g/kg/day dose level. The amended report also includes all data tables – both individual and summary.
- ⇒ 3M is submitting additional studies and documents which relate to the PFOS two-generation rat reproduction study (Sponsor's Study number 6295.9). These additional studies and documents are listed in Attachment A to this letter.

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Section 8(e) Coordinator
April 20, 2000
Page 2

Please do not hesitate to contact the undersigned at (651) 733-5181 or Dr. John Butenhoff, 3M Toxicology, at (651) 733-1962 for further information.

Sincerely,

A handwritten signature in black ink, appearing to read "L. Zobel MD MPH". The signature is stylized with a large, looped "L" and a distinct "Z".

Larry R. Zobel, MD MPH
Staff Vice President & Medical Director

Enclosures

cc: Dr. Charles Auer, Director Chemical Control Division

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Attachment A

Protocol 418-008 Combined oral (gavage) fertility, developmental and perinatal/postnatal reproduction toxicity study of PFOS in rats (Sponsor's study number: 6295.9), Table E20, 1-3.

Harb, R.V., Hartman, H.A., and Cox, R.H. (1994), Prevention of fluvastatin induced toxicity, mortality, and cardiac myopathy in pregnant rats by mevalonic acid supplementation. *Teratology*, **50**, 19-26

Haugthom, B. and Spydevold, O. (1992), The mechanism underlying the hyperlipemic effect of perfluorooctanoic acid (PFOA), perfluorooctane sulphonic acid (PFOS) and clofibric acid. *Biochimica et Biophysica Acta*, **1128**, 65-72.

Levin, M.S., Pitt, A.J.A., Schwartz, A.L., Edwards, P.A. and Gordon, J.I. (1989), Developmental changes in the expression of genes involved in cholesterol biosynthesis and lipid transport in human and rat fetal and neonatal livers. *Biochimica et Biophysica Acta*, **1003**, 293-300.

Final Report Protocol 418-013 Oral (Gavage) Pharmacokinetic Study of PFOS in Rats (Sponsor's study number: T-6295.12), June 24, 1999

Protocol FACT-TOX-110 Oral (Gavage) Pharmacokinetic Study of PFOS in Rats, Protocol, June 8, 1999

Final Report Protocol 418-015 Oral (Gavage) Pharmacokinetic Recovery Study of PFOS in Rats (Sponsor's study number: T-6295.14), July 23, 1999

Protocol FACT-TOX-111 Oral (Gavage) Pharmacokinetic Recovery Study of PFOS in Rats, Protocol, June 8, 1999

Summary PFOS Rat Two-Generation Reproduction Study (Study numbers: 3M T-6295.9, Argus 418-008 [in-life], FACT-TOX-012 [analytical])

Report Amendment I, 13 April 2000, Protocol 418-008 (Sponsor's study number: 6295.9) Combined Oral (Gavage) Fertility, Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFOS in Rats, Final Report

Analytical Laboratory Report on the Determination of the Presence and Concentration of Potassium Perfluorooctanesulfonate (CAS Number: 2759-39-3) in the Serum and Liver of Sprague-Dawley® Rats Exposed to PFOS via Gavage, Laboratory Report No. <U2006>, Requestor Project No. <3M TOX 6295.9>, October 27, 1999

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Interoffice Memo from Tom Kestner to Leo Gehlhoff, "Fluorochemical Isomer Distribution by ^{19}F -NMR Spectroscopy, December 1, 1997

Final Report Protocol 418-008 Combined Oral (Gavage) Fertility, Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFOS in Rats (Sponsor's study number 6295.9, June 10, 1999

Summary PFOS Rat Cross-Fostering (Study numbers: 3M T-6295.13, Argus 418-014)

Final Report Protocol 418-014, Oral (Gavage) Cross-Fostering Study of PFOS in Rats (Sponsor's study number: T-6295.13), July 23, 1999

Analytical Laboratory Report on the Determination of the Presence and Concentration of Perfluorooctanesulfonate (PFOS) (CAS Number: 2759-39-3) in the Serum of Sprague-Dawley® Rats Exposed to Potassium Perfluorooctanesulfonate via Gavage, Laboratory Report No. U2779, Requestor Project No. 3M Tox 6295.13, June 10, 1999

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