

3M Specialty Materials

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St. Paul, MN 55144-1000

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September 19, 2000

Ms. Vanessa Williams
EPA Document Control Office
US Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460-001

FYI-00-001378

85000000032

FAX 202-260-9555

Dear Ms. Williams:

Regarding an August 31, 2000 submission to EPA by 3M entitled "Information on Perfluorooctane Sulfonate and Related Compounds", one specific environmental study included in the submission was claimed as CBI. All other studies and information included in that submission are considered to be non-CBI by 3M.

Best regards,



William A. Weppner, Ph.D.
Director
Environmental, Health, Safety & Regulatory Affairs
Specialty Material Markets Group
3M Center, Bldg. 236-1B-10
St. Paul, MN 55144

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MR 34052
MR 39320

August 31, 2000

VIA OVERNIGHT DELIVERY

Dr. Charles Auer
Director
Chemical Control Division
Office Of Pollution Prevention And Toxics
United States Environmental Protection Agency
401 M Street, Southwest
Room 403 East Tower (Mail Code 7405)
Washington, D. C. 20460

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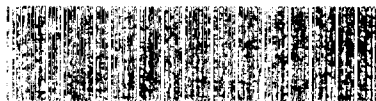
Re: **Information On Perfluorooctane
Sulfonates And Related Compounds**

Dear Charlie:

Pursuant to our recent communications, 3M is enclosing additional information on perfluorooctane sulfonates and related compounds. The enclosed information supplements information submitted to you previously, including our letters dated April 21, May 4, May 18, May 25, and June 28, 2000. Again, we are providing this information on a voluntary basis as part of our continuing discussions with EPA regarding fluorochemistry.

We are enclosing information on perfluorooctane sulfonates and related compounds that either post-dates our most recent submission or has been located as part of our continuing file search. The enclosed information includes:

- Copies of post-1976 studies and certain other information relating to the following health effects areas: (i) acute toxicity; (ii) genotoxicity; (iii) repeated-dose toxicity; (iv) pharmacokinetics; (v) teratology; and (vi) medical surveillance and epidemiology. We have organized this information in labeled file folders for each compound, and provided a detailed index, to aid EPA's review. Some acute studies are enclosed, while less significant acute studies appear only as bibliographic entries on the index. The index also notes a few minor corrections to earlier indices.
- Copies of post-1976 studies and certain other information relating to the following environmental science areas: (i) environmental fate and transport and (ii) environmental monitoring. These materials are contained in a separate file folder with an index in table form.



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One enclosed environmental document contains information that qualifies as confidential business information (CBI); we have enclosed a sanitized version of that document, and are submitting the unredacted version in a sealed envelope.

As in our prior submissions, many of the studies refer to the test substance only by a 3M product identification number with a "T", "L" or "FC" prefix. Although analysis of the test substance has been included where available, it is often not possible to determine from the study report itself the identity of the test substance. Thus, we have 3M's historical records keyed to the 3M product number to determine the composition of the test substance. Where available, the index provides composition information such as percent composition, solvent context, salt form and purity grade for compounds not so described in prior submissions. Please note that the term "narrow range" refers to a higher purity grade of a compound. Finally, it should be recognized that product formulations have evolved over the years; composition information may not be contemporaneous with the toxicology studies, and some of the test substances do not constitute current products.

3M is continuing its file review and will supplement the enclosed information as appropriate. 3M looks forward to discussing the enclosed information with you and other EPA staff. In the meantime, please do not hesitate to contact me with any questions.

Very truly yours



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Enclosures

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ATTACHMENT TO LETTER TO C. AUER DATED AUGUST 31, 2000
SUPPLEMENTAL SUBMISSION

TOXICOLOGY AND MEDICAL SURVEILLANCE

PFOS	Perfluorooctane sulfonate
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Medical Surveillance and Epidemiologic

1. Interim Report #1, Determination of Serum Half-Lives of Several Fluorochemicals, June 8, 2000 (*previously submitted to TSCA 8(e) docket, included here for convenience*)
2. Data regarding general population blood samples from several countries analyzed by 3M's Environmental Laboratory in 1999 (no report was prepared).

Acute Toxicity

The following pre-1976 study was listed in the bibliography of acute studies with a prior submission, but a copy is now being submitted for EPA's convenience:

1. Report by WARF Institute, Inc. and accompanying documentation, Primary Skin Irritation and Primary Eye Irritation in Albino Rabbits, Sample T-1117 (FC-95), November 7, 1974

Acute Toxicity (Bibliography Only – Copy Not Submitted)

1. Final Report, Acute Ocular Irritation Test with T-2997CoC in Albino Rabbits, Safety Evaluation Laboratory, Riker Laboratories, Inc., Study No. 0882EB0009, 3M Reference No. T-2997 (perfluoroethylcyclohexylsulfonate DEA salt), January 25, 1982.

Genotoxicity

1. Final Report, revised, In Vitro Microbiological Mutagenicity Assays of 3M Company Compound T-2816CoC, SRI International, SRI Study No. LSC-8958, 3M Reference No. T-2816CoC (PFOS DEA salt), March 1980.
2. Final Report, In Vitro Microbiological Mutagenicity Assays of 3M Company's Compound T-2997 CoC (perfluoroethylcyclohexylsulfonate DEA salt), SRI International, SRI Study No. LSC-8958, January 1981.

Teratology

Correction to May 25 Index: Materials provided were incorrectly indexed as Letter from E. Marshall Johnson to William C. McCormick. Index should read Letter from E. Marshall Johnson to Dr. Franklin D. Griffith, regarding Riker teratology studies on PFOS and ethyl FOSE, November 12, 1982.

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**ATTACHMENT TO LETTER TO C. AUER DATED AUGUST 31, 2000
SUPPLEMENTAL SUBMISSION**

Repeat Dose

1. Additional Data on 26-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS, 3M Reference T-6295):
 - a) Draft Pathology Report (Ancillary Study), Electron Microscopic Evaluation of Liver in Cynomolgus Monkeys (Recovery Animals), Study No. 6329-223, Pathology Associates International, PAI Study Number EM 99.76, May 30, 2000.
 - b) Data on TSH and Lipids in Cynomolgus Monkeys, Anilytics Incorporated, reported May 2, 2000, with accompanying correspondence including letter from Andrew Seacat, Ph.D. to Peter J. Thomford, Ph.D. dated March 6, 2000, and letter from Saroj R. Das, Ph.D. to Andrew Seacat, Ph.D. dated April 5, 2000 regarding methodology

Pharmacokinetic

1. The following study was previously identified in the list of published literature; a copy now being submitted for convenience:

An Investigation of the Effects of Fluorocarbons on Liver Fatty Acid-Binding Protein, thesis submitted to the Graduate School of the University of Minnesota, by Deanna J. Nabbefeld, April 1998.

Legend: FC1 = perfluorooctane sulfonic acid
FC2 = ammonium perfluorooctanoate
FC3 = N-Ethyl FOSE
FC4 = N-ethylperfluorooctane sulfonamide

2. Final Report, 28 Day Percutaneous Absorption Study with FC-98 in Albino Rabbits, Safety Evaluation Laboratory, Riker Laboratories, Inc., 3M Reference No. T-4980, (perfluoroethylcyclohexylsulfonate), Experiment No. 0979AB0630, March 15, 1981.
3. Final Report, Single-Dose Intravenous Pharmacokinetic Study of T-6684 in Rabbits, Corning Hazleton, Study No. CHW 6329-199, 3M Reference No. T-6684 (didecyldimethyl ammonium salt of PFOS), December 31, 1997.
4. Final Report, 5-Daily Dose Dermal Absorption/Toxicity Pharmacokinetic Study of T-6684 in Rabbits, Covance Laboratory, Study No. 6329-200, 3M Reference No. T-6684 (didecyldimethyl ammonium salt of PFOS), December 31, 1997. [Draft of this report was submitted to EPA with letter dated May 18, 2000.]

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**ATTACHMENT TO LETTER TO C. AUER DATED AUGUST 31, 2000
SUPPLEMENTAL SUBMISSION**

PFOS Mixtures	
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Acute Toxicity (Bibliography Only)

1. Final Report, Primary Eye Irritation Study in Rabbits, Hazelton Laboratories America, Inc., 3M Reference No. T-4016, January 28, 1987.
2. Final Report, Acute Oral Toxicity Study in Rats, Hazelton Laboratories America, Inc., 3M Reference No. T-4016, February 9, 1987.
3. Final Report, Primary Dermal Irritation Study in Rabbits, Hazelton Laboratories America, Inc., 3M Reference No. T-4016, February 27, 1987.

POSF	Perfluorooctanesulfonyl fluoride
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Ongoing Studies

1. Study Outline dated June 22, 2000 and Protocol dated December 30, 1998 for Pharmacokinetic Study of POSF in Rats, 3M Reference No. T-7098.1.

N-EtFOSE alcohol	N-ethyl perfluorooctane sulfonamidoethanol
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Acute Toxicity

1. Final Report, Acute Oral Toxicity (LD₅₀) Study in Rats, FM-3422, International Research and Development Corporation, 3M Reference No. T-2253, Study No. 137-084, June 7, 1978

Pharmacokinetic

1. Biotransformation of 14C-N-Ethyl FOSE in Rats After Administration in Feed for One Week, Riker Laboratories, Inc., January 28, 1983.

The copy of the following item is submitted under PFOS:

An Investigation of the Effects of Fluorocarbons on Liver Fatty Acid-Binding Protein, thesis submitted to the Graduate School of the University of Minnesota, by Deanna J. Nabbefeld, April 1998.

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**ATTACHMENT TO LETTER TO C. AUER DATED AUGUST 31, 2000
SUPPLEMENTAL SUBMISSION**

Teratology

1. Teratology Studies on FM 3422, 3M Reference T-3352:
 - a) Final Report, Pilot Rat Teratology Study, T-3352, Hazleton Laboratories America, Inc., Project No. 154-159, May 11, 1983.
 - b) Final Report, Rat Teratology Study, T-3352, Hazleton Laboratories America, Inc., Project No. 154-161, March 21, 1984.
 - c) Protocol, Rat Teratology Study (Segment II), T-3352, Hazleton Laboratories America, Inc., June 2, 1983.

Correction To May 25 Index: Materials provided were incorrectly indexed as Letter from E. Marshall Johnson to William C. McCormick. Index should read Letter from E. Marshall Johnson to Dr. Franklin D. Griffith, regarding Riker teratology studies on PFOS and ethyl FOSE, November 12, 1982

Ongoing

Note: Mechanistic research on N-ethyl FOSE, 3M Reference Nos. T-3616.10, FM 3923, is ongoing at the University of Minnesota under the direction of Kendall Wallace. Documents regarding this research were submitted with the May 4, 2000 submission on PFOS (*see* Mechanistic 1)(a)-(f)) but were not indexed under N-ethyl FOSE.

N-EtFOSA	N-ethyl perfluorooctanesulfonamide
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Acute Toxicity

1. Final Report, Acute Oral Toxicity Screen with T-3067CoC in Albino Rats, Safety Evaluation Laboratory, Riker Laboratories, Inc., Experiment No. 0981AR0147, 3M Reference No. T-3067 (narrow range ethyl FOSA), May 15, 1987.

Correction to May 18 Submission: Three studies conducted by Corning Hazelton (CHW 61101149, CHW 61101150, and CHW 61101151) were erroneously listed on the May 18, 2000 bibliography under N-EtFOSA (Acute Toxicity bibliography only items 1 – 3). These studies should not have been listed there. They did correctly appear on the May 18 bibliography under PFOS and were provided under PFOS Acute Toxicity 1(a)-(c).

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**ATTACHMENT TO LETTER TO C. AUER DATED AUGUST 31, 2000
SUPPLEMENTAL SUBMISSION**

Pharmacokinetic

1. Final Report, Single-Dose Intravenous Pharmacokinetic Study of T-5904 in Rabbits, Hazleton Wisconsin, 3M Reference No. T-5904 (95-99%), Study No. HWI 6329-117, October 14, 1994.

Submitted above under PFOS:

An Investigation of the Effects of Fluorocarbons on Liver Fatty Acid-Binding Protein, thesis submitted to the Graduate School of the University of Minnesota, by Deanna J. Nabbefeld, April 1998.

Ongoing

Mechanistic research at the University of Minnesota under the direction of Kendall Wallace includes N-Et FOSA, 3M Reference No. T-6868.1. Documents regarding this research have been previously submitted with the May 4, 2000 submission on PFOS (see Mechanistic 1)(a)-(f)).

PFHS	Perfluorohexane sulfonate
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Medical Surveillance and Epidemiologic

See item 1 under PFOS: Interim Report #1, Determination of Serum Half-Lives of Several Fluorochemicals, June 8, 2000.

FOSA or PFOSA	Perfluorooctanesulfonamide
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Medical Surveillance and Epidemiologic

See item 1 under PFOS: Interim Report #1, Determination of Serum Half-Lives of Several Fluorochemicals, June 8, 2000.

Ongoing - Pharmacokinetic

1. Protocol for Study No. T-7132.2; ST-39, Pharmacokinetic Study of Perfluorooctane Sulfonamide in Rats, 3M Medical Department, Corporate Toxicology Laboratory, In-Life End Date November 2, 1999, report on in-life study pending. We are providing a copy of the Laboratory Report, Analytical Report of Data for PFOSA Pharmacokinetic Study in Rats (Sera and Liver), 3M Environmental Laboratory, Laboratory Report No. FACT-TOX-145 (W2814), 3M Reference No. T-7132.2, December 6, 1999.

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**ATTACHMENT TO LETTER TO C. AUER DATED AUGUST 31, 2000
SUPPLEMENTAL SUBMISSION**

PFOSAA	Perfluorooctane sulfonylamido (ethyl)acetate
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Medical Surveillance and Epidemiologic

See item 1 under PFOS: Interim Report #1, Determination of Serum Half-Lives of Several Fluorochemicals, June 8, 2000.

Acute Toxicity (Bibliography Only)

1. Final Report, Acute Oral Toxicity Study in Rats, Hazleton Laboratories America, Inc., Study No. 70905392, 3M Reference No. T-4101, FC-109 (19-23% PFOSAA Potassium salt in water), January 21, 1988.
2. Final Report, Acute Dermal Toxicity Study in Rabbits (OECD Guidelines), Hazleton Laboratories America, Inc., Study No. 70905393, 3M Reference No. T-4101, FC-109 (19-23% PFOSAA Potassium salt in water), January 18, 1988.
3. Final Report, Primary Dermal Irritation/Corrosion Study in Rabbits, Hazleton Laboratories America, Inc., Study No. 70905394, 3M Reference No. T-4101, FC-109 (19-23% PFOSAA Potassium salt in water), January 18, 1988.
4. Final Report, Primary Eye Irritation/Corrosion Study in Rabbits, Hazleton Laboratories America, Inc., Study No. 70905395, 3M Reference No. T-4101, FC-109 (19-23% PFOSAA Potassium salt in water), January 18, 1988.

Ongoing

Mechanistic research at the University of Minnesota under the direction of Kendall Wallace includes PFOSAA, 3M Reference No. T-6896.1. Documents regarding this research have been previously submitted with the May 4, 2000 submission on PFOS (*see* Mechanistic 1)(a)-(f)).

PFOA	Perfluorooctanoic acid
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Medical Surveillance and Epidemiologic

See item 1 under PFOS: Interim Report #1, Determination of Serum Half-Lives of Several Fluorochemicals, June 8, 2000.

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**ATTACHMENT TO LETTER TO C. AUER DATED AUGUST 31, 2000
SUPPLEMENTAL SUBMISSION**

Acute Toxicity

1. Final Report, Acute Oral Toxicity Study in Rats, Hazleton Laboratories America, Study No. HLA 91201739, 3M Reference No. T-4416 (approximately 45% FC-143 solids – $C_7H_{15}COO-NH_4^+$, 2.2% homologs, 50% water, 2.5% inerts), April 2, 1990.
2. Final Report, Primary Dermal Irritation/Corrosion Study in Rabbits (OECD Guidelines), Hazleton Laboratories America, Study No. HLA 91201740, 3M Reference No. T-4416, February 14, 1990.
3. Final Report, Primary Eye Irritation/Corrosion Study in Rabbits (OECD Guidelines), Hazleton Laboratories America, Study No. HLA 91201740, 3M Reference No. T-4416, February 28, 1990.

Genotoxicity

1. Final Report, Mutagenicity Test on T-6358 Measuring Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells, Corning Hazleton Inc., Study No. 17388-0-437, 3M Reference No. T-6358, FC-143, Lot 332, April 25, 1996, with protocol.
2. Final Report, Mutagenicity Test on T-6358 in an *In Vivo* Mouse Micronucleus Assay, Corning Hazleton Inc., Study No. 17388-0-455, 3M Reference No. T-6358, FC-143, Lot 332, May 14, 1996, with protocol and protocol amendments.

Pharmacokinetics

Submitted above under PFOS:

An Investigation of the Effects of Fluorocarbons on Liver Fatty Acid-Binding Protein, thesis submitted to the Graduate School of the University of Minnesota, by Deanna J. Nabbefeld, April 1998

Ongoing

1. Mechanistic research at the University of Minnesota under the direction of Kendall Wallace includes PFOA, 3M Reference No. T-6889.1. Documents regarding this research have been previously submitted with the May 4, 2000 submission on PFOS (see Mechanistic 1)(a)-(f)).

**ATTACHMENT TO LETTER TO C. AUER DATED AUGUST 31, 2000
SUPPLEMENTAL SUBMISSION**

ENVIRONMENTAL

Title	Laboratory or Author	Completion Date	Type
Fluorochemical Characterization of Surface Water Samples Columbus, GA (W2336)	Centre Analytical Laboratories, Inc.	5/24/00	Final Report
Fluorochemical Characterization of Surface Water Samples Cleveland, TN (W1973)	Centre Analytical Laboratories, Inc.	5/24/00	Final Report
Fluorochemical Characterization of Surface Water Samples Decatur, AL (W1979)	Centre Analytical Laboratories, Inc.	5/24/00	Final Report
Fluorochemical Characterization of Surface Water Samples Mobile, AL (W2151)	Centre Analytical Laboratories, Inc.	5/24/00	Final Report
Fluorochemical Characterization of Surface Water Samples Pensacola, FL (W2176)	Centre Analytical Laboratories, Inc.	5/24/00	Final Report
Fluorochemical Characterization of Surface Water Samples Port St. Lucie, FL (W2363)	Centre Analytical Laboratories, Inc.	5/24/00	Report
Fluorochemical Characterization of Surface Water Samples Port St. Lucie, FL (W2363)	Centre Analytical Laboratories, Inc.	August, 2000	Final Report
Final Multi-City Study. Field Report for Mobile Alabama and Pensacola Florida – Battelle Duxbury Activities	Battelle Memorial Institute	9/29/99 (Addendum signed on 10/13/99)	Final Report
Final Multi-City Study. Field Report for Cleveland Tennessee and Decatur Alabama – Battelle Duxbury Activities	Battelle Memorial Institute	7/9/99 (Addendum signed on 12/6/99)	Final Report
Final Multi-City Study. Field Report for Columbus Georgia and Port St. Lucie Florida – Battelle Duxbury Activities	Battelle Memorial Institute	10/26/99 (Addendum signed on 12/6/99)	Final Report
Port St. Lucie Florida Water and Sediment Resample for the Empirical Human Exposure Assessment Multi-City Study	Pace Analytical Services, Inc.	8/15/00	Report
Sulfonated Perfluorochemicals: U.S. Release Estimation – 1997 Part 1: Life-Cycle Waste Stream Estimates – Executive Summary	Battelle Memorial Institute	4/21/2000	Final Report

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