

AR 226-1512

9 pp



VIA HAND DELIVERY

July 9, 2003

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Docket AR-226
EPA East, Room 6428
1201 Constitution Avenue, NW
Washington, DC 20460
Phone: 202-564-8930

RECEIVED
OPPT/MCIC
2003 SEP 12 AM 8:34Attention: OPPT Docket No. AR-226

Re: Information on Perfluorooctane Sulfonate,
Perfluorooctanoic Acid, and Related Compounds

Dear Sir or Madam:

This continues 3M's voluntary submissions of data on perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA), and related compounds, as part of our ongoing dialogue with EPA regarding perfluorochemicals.

We are enclosing a number of studies, which are listed on the enclosed index. As in our past submissions, we have organized the studies by chemical, and within the sections for each chemical, by endpoint or type of study. This submission includes studies related to PFOS, PFOA, and other compounds, and also includes studies that address multiple compounds. Please note that we are submitting a copy of the Protein Binding Study report that is redacted to remove non-responsive confidential business information. We also have included a bibliography of recently published literature, updating the references we have previously provided. We have not included in this bibliography abstracts of presentations to the Society of Toxicology or the Society of Environmental Toxicology and Chemistry.

We enclose paper copies of documents with this letter. We will provide a CD containing our 2002 and 2003 paper submissions in the near future.

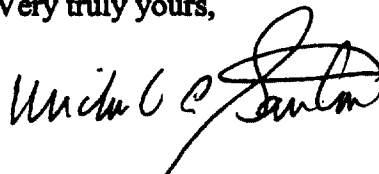
As I discussed with Ms. Mary Dominiak of EPA on May 1, 2003, 3M will continue its practice of submitting data when final reports are available, and hence we are not providing various raw data in our possession at this time. We will continue to submit final reports to the AR-226 docket as they are available.

CONTAIN NO CP

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Please feel free to contact me with any questions.

Very truly yours,

A handwritten signature in black ink, appearing to read "Michael A. Santoro", written in a cursive style.

Michael A. Santoro
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Safety and Regulatory Affairs
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cc: Dr. Charles Auer (Room 4146)
Dr. Oscar Hernandez

**ATTACHMENT TO LETTER OF JULY 9, 2003
3M FLUOROchemical SUBMISSION**

3M FLUOROchemical SUBMISSION

TOXICOLOGY, EPIDEMIOLOGY AND MEDICAL SURVEILLANCE

Multiple Chemicals	
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Human Sera/Medical Surveillance/Epidemiology

1. Final Report, NIOSH Health Hazard Evaluation for Perfluorooctanoic Acid and Perfluorooctane Sulfonate, NIOSH HETA 20010235, July 31, 2001.
2. Final Report, Assessment of Lipid, Hepatic and Thyroid Function in Relation to an Occupational Biologic Limit Value for Perfluorooctanoic Acid, 3M Medical Department, June 9, 2003.
3. Final Report, Descriptive Analysis of Serum Fluorochemical Concentrations from Cottage Grove Employee Participants of the 2002 Medical Surveillance Program, 3M Medical Department, June 17, 2003.
4. Final Report, Descriptive Analysis of Serum Fluorochemical Concentrations from Decatur Employee Participants of the 2002 Medical Surveillance Program, 3M Medical Department, June 17, 2003.

Pharmacokinetic Studies

1. Protein Binding of Perfluorohexane Sulfonate, Perfluorooctane Sulfonate and Perfluorooctanoate to Plasma (Human, Rat, and Monkey), and Various Human-Derived Plasma Protein Fractions, Southern Research Institute Study ID 9921.7, 3M Reference Nos. T-6295.33, T-7485.18, T-7504.4, and T-7507.4, June 3, 2003. [Copy for docket redacted to remove non-responsive confidential business information]

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PFOS	Perfluorooctanesulfonate
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Repeated-Dose Toxicity

1. 4-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295) in Cynomolgus Monkeys, Covance Study No. 6329-222, 3M Reference No. T-6295.6, April 9, 2002.

Pharmacokinetic Studies

1. A Pharmacokinetic Study of Potassium Perfluorooctanesulfonate in the Cynomolgus Monkey, Southern Research Institute Study ID 9921.6, 3M Reference No. T-6295, April 22, 2003.

Reproductive

1. One Generation Reproduction Study of PFOS – Mevalonic Acid/Cholesterol Challenge and NOEL Investigation in Rats, 3M Reference No. T-6295.25, December 16, 2002.

POSF	Perfluorooctanesulfonyl fluoride
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Acute Toxicity

1. Acute Inhalation Limit Toxicity Study of Perfluorooctanesulfonyl Fluoride (POSF) T-7098.3, 3M Reference No. T-7098.3, October 18, 2001.

Genotoxicity

1. Perfluorooctanesulfonyl Fluoride (POSF) In Vitro Mammalian Chromosome Aberration Test in Human Lymphocyte (Huntingdon Study No. MIN 315/022356), 3M Reference No. T-7661.3, October 22, 2002.
2. Perfluorooctanesulfonyl Fluoride (POSF) Bacterial Reverse Mutation Test (Huntingdon Study No. MIN 314/022208), 3M Reference No. T-7661.2, October 23, 2002.

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PFHS	Perfluorohexane sulfonate
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Pharmacokinetic Study

1. A Pharmacokinetic Study of Potassium Perfluorohexanesulfonate in the Cynomolgus Monkey, Southern Research Institute Study ID 9921.5, 3M Reference No. T-7504, April 22, 2003.

PFOA	Perfluorooctanoic acid
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Pharmacokinetic Study

1. A Pharmacokinetic Study of Potassium Perfluorooctanoate in the Cynomolgus Monkey, Southern Research Institute Study ID 9921.4, 3M Reference No. T-6889, January 14, 2003.

N-EtFOSE	N-Ethylperfluorooctane sulfonamidoethanol
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Reproductive

1. Two Generation Rat Reproduction Study
 - a. Report Amendment, Combined Oral (Gavage) Fertility, Developmental and Perinatal/Postnatal Reproduction Toxicity Study of N-EtFOSE in Rats – Correction to Text Figure 1, 3M Reference No. T-6316.5, October 12, 2000.

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ENVIRONMENTAL STUDIES

Multiple Chemicals	
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1. Tennessee River Study
 - a. Data Evaluation, A Survey of Selected Fluorochemicals in the Decatur Alabama Area - 2002 Sampling, Entrix, Inc. Project No. 178401, July 2003.
 - b. Analytical Laboratory Report, Tennessee River Valley Samples, 3M Environmental Laboratory Study # E02-0443, Revised Report, January 6, 2003.

PFOS	Perfluorooctanesulfonate
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1. Incineration Study
 - a. Robust Summary, Laboratory-Scale Thermal Degradation of Perfluoro-Octanyl Sulfonate and Related Precursors, July 3, 2003.
 - b. Final Report, Laboratory-Scale Thermal Degradation of Perfluoro-Octanyl Sulfonate and Related Precursors, Environmental Sciences and Engineering Group, University of Dayton Research Institute, June 19, 2003.
2. Terrestrial Plant Toxicity Study
 - a. Robust Summary, Toxicity to Terrestrial Plants, June 3, 2003.
 - b. Final Report, PFOS: A Toxicity Test to Determine the Effects of the Test Substance on Seedling Emergence of Seven Species of Plants, Wildlife International, Ltd. Project No. 454-110, May 30, 2003.
 - c. Analytical Laboratory Report, Analytical Method Validation for the Determination of Perfluorooctanesulfonate, Potassium Salt (PFOS) in Artificial Soil, Wildlife International, Ltd. Project No. 454C-120, May 27, 2003.
 - d. Analytical Laboratory Report, Analytical Method Validation for the Determination of Perfluorooctanesulfonate, Potassium Salt (PFOS) in Plant Tissues, Wildlife International, Ltd. Project No. 454C-125, October 22, 2001.

BIBLIOGRAPHY OF PUBLISHED LITERATURE

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Austin ME, Badrinarayanan SK, Barber M, Kannan K, MohanKumar PS, and MohanKumar SMJ (2003). Neuroendocrine Effects of Perfluorooctane Sulfonate in Rats. *Environ. Health Persp.* doi: 10.1289/ehp.6128 (available at <http://dx.doi.org>) online April 3, 2003.

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Butenhoff J, Costa G, Elcombe C, Farrar D, Hansen K, Iwai H, Jung R, Kennedy G, Lieder P, Olsen G, and Thomford P (2002). Toxicity of Ammonium Perfluorooctanoate in Male Cynomolgus Monkeys after Oral Dosing for 6 Months. *Toxicol. Sci.* 69:244-57.

Luebker DJ, Hansen KJ, Bass NM, Butenhoff JL, and Seacat AM (2002). Interactions of Fluorochemicals with Rat Liver Fatty Acid-Binding Protein. *Toxicol.* 176:175-85.

Masunaga S, Kanan K, Doi R, Nakanishi J, Giesy JP (2002). Levels of Perfluorooctane Sulfonate (PFOS) and Other Related Compounds in the Blood of Japanese People. *Organohalogen Compounds* 59:319-322.

Olsen GW, Burris JM, Burlew MM, Mandel JH (2003). Epidemiologic Assessment of Worker Serum Perfluorooctanesulfoante (PFOS) and Perfluorooctanoate (PFOA) Concentrations and Medical Surveillance Examinations. *JOEM* 45:260-270.

Olsen GW, Hansen KJ, Stevenson LA, Burris JM, and Mandel JH (2003). Human Donor Liver and Serum Concentrations of Perfluorooctanesulfonate and Other Perfluorochemical, *Environ. Sci. & Technol.* 37(5):888-91.

Seacat AM, Thomford PJ, Hansen KJ, Olsen GW, Case MT, Butenhoff JL (2002). Subchronic Toxicity Studies on Perfluorooctanesulfonate Potassium Salt in Cynomolgus Monkeys. *Toxicol. Sci.* 68:249-264.

Seacat AM, Thomford PJ, Hansen KJ, Clemen LA, Eldridge SR, Elcombe CR, and Butenhoff JL (2003). Sub-chronic Dietary Toxicity of Potassium Perfluorooctanesulfonate in Rats. *Toxicol.* 183:117-31.

Starkov AA, Wallace KB (2002). Structural Determinants of Fluorochemical-Induced Mitochondrial Function. *Toxicol. Sci.* 66:244-252.

ENVIRONMENTAL

Bonifacio RP, Padua A, and Costa-Gomes MF (2001). Perfluoroalkanes in Water: Experimental Henry's Law Coefficients for Hexafluoroethane and Computer Simulations for Tetrafluoromethane and Hexafluoroethane. *J. Phys. Chem.* 105:8403-03.

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Golovanov IB and Tsygankova IG (2001). Structure-Property Correlation Equation: VII. Some Properties of Perfluorinated Organic Compounds. *Russian J. of Gen. Chem.* 71(6):839-44.

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Hebert GN, Odom MA, Craig PS, Dick DL, and Straus SH (2002). Method for the determination of sub-ppm concentrations of perfluoroalkylsulfonate anions in water. Department of Chemistry, Colorado State University, Fort Collins, CO 80523.

Hoff PT, Vijver K, Dongen W, Esmans EL, Blust R, and Coen WM (2003). Perfluorooctane Sulfonic Acid in Bib (Trisopterus luscus) and Plaice (Pleuronectes platessa) from the Western Scheldt and the Belgian North Sea: Distribution and Biochemical Effects. *Environ. Toxicol. and Chem.* 22(3):608-14.

Hu W, Jones PD, Upham BL, Trosko JE, Lau C, and Giesy JP (2002). Inhibition of Gap Junctional Intercellular Communication by Perfluorinated Compounds in Rat Liver and Dolphin Kidney Epithelial Cell Lines in Vitro and Sprague-Dawley Rats in Vivo. *Toxicol. Sci.* 68:429-36.

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