

AR 226-1717



May 11, 2004

TSCA Non-Confidential Information Center (7407T)
Office of Pollution Prevention and Toxics (OPPT)
Docket AR-226
EPA West Building, Room B-146
1301 Constitution Ave., N.W.
Washington, DC 20460
Phone: 202-566-0280

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2004 MAY 12 AM 8:17

Attention: 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 for the docket paper copies of a number of studies, or in the case of a collection of bird studies, a CD of electronic copies. The studies are itemized 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.

With respect to the environmental studies, please note that this submission includes revised reports on the Tennessee River study which should replace those we submitted in July 2003. In addition, we have included in this submission addenda to a number of PFOS ecotoxicological studies correcting reported values based on a new analysis of the purity of the sample material used in the tests. The more recent analysis identified additional impurities in the test material and thus revised the sample purity slightly downward. We have provided the AR226 docket reference for each of the studies to which these addenda pertain. We are also providing a table summarizing the changes to each study report.

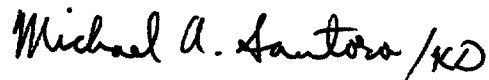
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Consistent with our past practice, we have included a bibliography of recently published literature in 3M's possession. Given the amount of published literature and its ready availability to EPA, we intend to discontinue the bibliography listing in future submissions.

We will also be providing under separate cover in the near future 3M's CD#6 of its AR-226 submissions, containing copies of all submissions from February 2002 through this May, 2004 submission.

We look forward to continuing our dialogue with the Agency. Please feel free to contact me with any questions.

Very truly yours,

Handwritten signature of Michael A. Santoro in black ink, followed by a handwritten initials "KD" in the same ink.

Michael A. Santoro
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Safety and Regulatory Affairs
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cc: Dr. Charles Auer
Dr. Oscar Hernandez
(without enclosures)

3M FLUOROCHEMICAL SUBMISSION

TOXICOLOGY, EPIDEMIOLOGY AND MEDICAL SURVEILLANCE

Multiple Chemicals	
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Human Sera/Medical Surveillance/Epidemiology

- 226-1719
1. Final Report, Descriptive Analysis of Serum Perfluorooctanoate (PFOA) and Perfluorooctanesulfonate (PFOS) Concentrations of Antwerp Employee Participants from the 2003 Fluorochemical Medical Surveillance Program, 3M Medical Department, August 14, 2003.
- 226-1720
2. Sample Analysis Report for Protocol EPI-0012, Quantitative Determination of PFOS and Related Compounds in Human Serum by LC/MS/MS, Northwest Bioanalytical Study No. NWBS00-091, November 21, 2001.
- 226-1721
3. Sample Analysis Report for Protocol EPI-PEuro, Quantitative Determination of PFOS, PFOSA, PFOSAA, PFHS, POAA, M556 and M570 in Human Serum by LC/MS/MS, Northwest Bioanalytical Study No. NWBS99-117, December 9, 1999.
- 226-1722
4. Sample Analysis Report for Protocol EPI-Swed, Quantitative Determination of PFOS, PFOSA, PFOSAA, PFHS, POAA, M556 and M570 in Human Serum by LC/MS/MS, Northwest Bioanalytical Study No. NWBS99-116, December 9, 1999.

Pharmacokinetic Study

- 226-1723
1. Final Report, Xenochemical Receptor trans-Activation by Perfluorooctane-based Chemicals, Boston University Department of Biology, 3M Reference No. T-6295.35, September 12, 2001.

PFOS	Perfluorooctane sulfonate
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Pharmacokinetic, Mechanism and Other Studies

- 226-1724
1. Final Report, An Investigation of the Mechanism of Toxicity in Adult Rats Exposed to High Levels of Perfluorooctanesulfonate (PFOS), 3M Project No. T-6295.31, April 23, 2004.
- 226-1725
2. Final Report, Analysis of Liver Enzymes, Glycogen, and Perfluorooctane Sulfonate (PFOS) Concentration in Samples from T-6295.25: One-Generation Reproduction Study

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of PFOS – Mevalonic Acid/Cholesterol Challenge and NOEL Investigation in Rats, 3M Project No. T-6295.28, April 23, 2004.

- 226-1726
3. Final Report, Determination of Possible Interference of Perfluorooctane Sulfonic Acid Potassium Salt with Rat Cholesterol, 3M Project No. 6329.263, August 17, 1999.

PFOA	Perfluorooctanoate
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- 226-1727
1. "Genotoxicity, Carcinogenicity, Developmental Effects and Reproductive Effects of Perfluorooctanoate: A Perspective from Available Animal and Human Studies," Association of Plastics Manufacturers of Europe and The Society of the Plastics Industry, December 12, 2002. *[previously submitted to EPA but we have not been able to locate in the docket]*

POSF	Perfluorooctanesulfonyl fluoride
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Repeat Dose

- 226-1728
1. Final Report, Oral Toxicity Rangefinder for Perfluorooctane Sulfonyl Fluoride (POSF) in Rats, 3M Study No. T-7098.2, May 11, 2001.

Pharmacokinetic Study

- 226-1729
1. Final Report, Acute Inhalation Toxicokinetic Study of Perfluorooctanesulfonyl Fluoride (POSF), 3M Study No. T7098.4, November 9, 2001.

PFHS	Perfluorohexane sulfonate
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Repeat-Dose

- 226-1730
1. Final Report, Oral (Gavage) Combined Repeated Dose Toxicity Study of T-7706 with the Reproduction/Developmental Toxicity Screening Test, Argus Research Protocol No. 418-028, 3M Reference No. T-7706, July 31, 2003.

FOSA	Perfluorooctanesulfonamide
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Pharmacokinetics and Mechanism Studies

- 226-1731
1. Final Report, Comparative Molecular Biology of Perfluorooctanesulfonamide (FOSA, T-7132) in Rats Following Four Consecutive Days of Dosing, Study No. DT15, 3M Reference No. T-7132, February 18, 2004.

ENVIRONMENTAL STUDIES

Multiple Chemicals	
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Environmental Monitoring

1. Revised Tennessee River Study (replaces versions submitted July 2003)
- 226-1732
a. Revised Report, A Survey of Selected Fluorochemicals in the Decatur Alabama Area - 2002 Sampling, Entrix, Inc. Project No. 178401, November 2003. (replaces the previously submitted Docket No. AR226-1364)
- 226-1733
b. Revised Analytical Laboratory Report, Tennessee River Valley Samples, 3M Environmental Laboratory Study # E02-0443, September 12, 2003. (replaces the previously submitted Docket No. AR226-1365)

PFOS	Perfluorooctane sulfonate
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Ecotoxicity Studies

1. Avian In-life Studies
- a. Mallard Duck Acute Study
- 226-1734
i. Toxicological Summary, PFOS – Dietary Acute Mallard Study, May 5, 2004.
- 226-1735
ii. Final Report, PFOS: A Dietary LC50 Study with the Mallard, Wildlife International, Ltd. Project No. 454-102, March 24, 2004.
- 226-1736
iii. Analytical Report, Laboratory Report Revision 1: Analytical Report of Data for PFOS Dietary LC50 Study with Mallards (Sera and Liver), 3M Environmental Laboratory No. FACT-TOX-130, March 23, 2001.

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b. Mallard Duck Pilot Study

226-1737 i. Toxicological Summary, PFOS – Dietary Chronic Pilot Reproductive Study: Mallard, May 5, 2004.

226-1738 ii. Final Report, PFOS: A Pilot Reproduction Study with the Mallard, Wildlife International, Ltd. Project No. 454-105, March 24, 2004.

226-1739 iii. Analytical Report, Extraction of Potassium Perfluorooctanesulfonate from Mallard Serum and Mallard Liver for Analysis Using HPLC-Electrospray/Mass Spectrometry (Mallard Pilot Study Samples), Centre Study No. 023-042, September 10, 2001.

226-1740 iv. Analytical Report, Extraction of Potassium Perfluorooctanesulfonate from Egg Membrane, Albumen, and Yolk for Analysis Using HPLC-Electrospray/Mass Spectrometry (Quail and Mallard Pilot Studies samples), Centre Study No. 023-063, September 10, 2001.

c. Mallard Duck Definitive Study

226-1741 i. Toxicological Summary, PFOS – Dietary Chronic Definitive Reproductive Study: Mallard, May 5, 2004.

226-1742 ii. Final Report, PFOS: A Reproduction Study with the Mallard, Wildlife International, Ltd. Project No. 454-109, March 24, 2004.

226-1743 iii. Analytical Report, Analytical Phase Report for PFOS: A Reproduction Study with the Mallard (Mallard Definitive Study Sera and Liver Analyses), 3M Environmental Laboratory Study # E01-1256, January 22, 2003.

226-1744 iv. Analytical Report, Extraction of Potassium Perfluorooctanesulfonate from Red Blood Cells and Serum for Analysis Using HPLC-Electrospray/Mass Spectrometry (Samples from Definitive Mallard and Quail Reproduction Studies), Exygen Study No. 023-066, June 12, 2003.

226-1745 v. Analytical Report, Analysis of Perfluorooctanesulfonate in Mallard and Quail Egg Yolk (Mallard and Quail Definitive Reproduction Study Eggs), Exygen Study No. 023-070, July 5, 2002.

d. Northern Bobwhite Quail Acute Study

226-1746 i. Toxicological Summary, PFOS – Dietary Acute Northern Bobwhite Study, May 5, 2004.

226-1747 ii. Final Report, PFOS: A Dietary LC50 Study with the Northern Bobwhite, Wildlife International, Ltd. Project No. 454-103, March 24, 2004.

- 226-1748 iii. Analytical Report, Laboratory Report Revision 1: Analytical Report of Data for PFOS Dietary LC50 Study in Northern Bobwhite (Sera and Liver), 3M Environmental Laboratory No. FACT-TOX-129, March 23, 2001.
- c. Northern Bobwhite Quail Pilot Study
- 226-1749 i. Toxicological Summary, PFOS – Dietary Chronic Pilot Reproductive Study: Northern Bobwhite, May 5, 2004.
- 226-1750 ii. Final Report, PFOS: A Pilot Reproduction Study with the Northern Bobwhite, Wildlife International, Ltd. Project No. 454-104, March 24, 2004.
- 226-1751 iii. Analytical Report, Extraction of Potassium Perfluorooctanesulfonate from Quail Serum and Quail Liver for Analysis Using HPLC-Electrospray/Mass Spectrometry (Quail Pilot Study Samples), Centre Study No. 023-041, September 10, 2001.
- f. Northern Bobwhite Quail Definitive Study
- 226-1752 i. Toxicological Summary, PFOS – Dietary Chronic Definitive Reproductive Study: Northern Bobwhite, May 5, 2004.
- 226-1753 ii. Final Report, PFOS: A Reproduction Study with the Northern Bobwhite, Wildlife International, Ltd. Project No. 454-108, March 24, 2004.
- 226-1754 iii. Analytical Report, Analytical Phase Report for PFOS: A Reproduction Study with the Northern Bobwhite (Quail Definitive Study Sera and Liver Analyses), 3M Environmental Laboratory Study # E01-1245, April 18, 2003.
2. Bluegill Study
- 226-1755 a. Robust Summary, Acute Toxicity to Bluegill Sunfish, 3M, April 14, 2004.
- 226-1756 b. Analytical Report, 96-Hour Static Bluegill Toxicity Test: Aquatic Toxicity Data Sheet (FC-95), 3M, May 27, 1978.

Analytical Purity Revisions to Ecotox Studies

- 226-1757. Summary Table, PFOS Ecotoxicological Testing Results Comparison of Effect Concentrations Calculated Using Different Sample Purity, May 2004
2. Addenda to Previously Submitted Reports Revised to Reflect the Most Recent PFOS Purity Analyses
- 226-1758 a. Addendum, PFOS: A 96-Hour Static Acute Toxicity Test with the Saltwater Mysid (

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Mysidopsis bahia), Wildlife International, Ltd. Project No. 454A-101, September 27, 2000 [Addendum to AR226-0095].

226-1759 b. Addendum, PFOS: A 96-Hour Static Acute Toxicity Test with the Fathead Minnow (*Pimephales promelas*), Wildlife International, Ltd. Project No. 454A-102, September 27, 2000 [Addendum to AR226-0083].

226-1760 c. Addendum, PFOS: A 96-Hour Toxicity Test with the Freshwater Alga (*Selenastrum capricornutum*), Wildlife International, Ltd. Project No. 454A-103A, September 27, 2000 [Addendum to AR226-0085].

226-1761 d. Addendum, PFOS: A 48-Hour Static Acute Toxicity Test with the Cladoceran (*Daphnia magna*), Wildlife International, Ltd. Project No. 454A-104, September 27, 2000 [Addendum to AR226-0087].

226-1762 e. Addendum, PFOS: A 96-Hour Static Acute Toxicity Test with the Freshwater Mussel (*Unio complanatus*), Wildlife International, Ltd. Project No. 454A-105, September 27, 2000 [Addendum to AR226-0091].

226-1763 f. Addendum, PFOS: A 96-Hour Shell Deposition Test with the Eastern Oyster (*Crassostrea virginica*), Wildlife International, Ltd. Project No. 454A-106, September 27, 2000 [Addendum to AR226-0089].

226-1764 g. Addendum, PFOS, A Flow-Through Life-Cycle Toxicity Test with the Saltwater Mysid (*Mysidopsis bahia*), Wildlife International, Ltd. Project No. 454A-107, September 27, 2000 [Addendum to AR226-0101].

226-1765 h. Addendum, PFOS: An Early Life-Stage Toxicity Test with the Fathead Minnow (*Pimephales promelas*), Wildlife International, Ltd. Project No. 454A-108, September 27, 2000 [Addendum to AR226-0097].

226-1766 i. Addendum, PFOS: A Semi-Static Life-Cycle Toxicity Test with the Cladoceran (*Daphnia magna*), Wildlife International, Ltd. Project No. 454A-109, September 27, 2000 [Addendum to AR226-0099].

226-1767 j. Addendum, Non-GLP Study: Determination of the Solubility of PFOS in Wildlife International, Ltd. Freshwater, Freshwater Algal Medium, and Saltwater, Wildlife International, Ltd. Project No. 454C-101-1, November 27, 2000 [Not previously submitted to the AR226 docket].

226-1768 k. Addendum, Determination of the Water Solubility of PFOS by the Shake Flask Method, Wildlife International, Ltd. Project No. 454C-107, November 27, 2000 [Addendum to AR226-0052].

226-1769 l. Addendum, PFOS: An Activated Sludge, Respiration Inhibition Test, Wildlife International, Ltd. Project No. 454E-101, December 1, 2000 [Addendum to AR226-0093].