

AR226-0003

April 21, 2000

3M

Dr. Charles Auer
Room 7405
US EPA Headquarters
Ariel Rios Bldg.
1200 Pennsylvania Avenue, N. W.
Washington, D. C. 20460

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MR 35339

Dear Charlie:

Pursuant to our recent communications, 3M is enclosing additional information relating to perfluorooctanesulfonate (PFOS). We are providing this information to you on a voluntary basis as part of our continuing discussions with EPA regarding fluorochemistry. This information includes studies on PFOS relating to the following areas: (i) pharmacokinetics; (ii) teratology; and (iii) epidemiology and medical surveillance. A listing of the enclosed studies has been attached to this letter, and summaries also have been provided for each category of studies. Please note that incorrectly applied legends relating to legal privileges and proprietary protections have been removed from certain documents. Finally, you should be receiving under separate cover additional studies on PFOS relating to reproductive toxicology that 3M will also be submitting to the TSCA Section 8(e) docket.

3M plans to provide you with additional information on PFOS and other fluorochemicals in the near future. In this regard, we have been trying to contact you to address scope and procedural matters, and we hope to talk with you the week of April 24, 2000.

Please do not hesitate to call me or Dr. Larry Zobel, 3M's Medical Director, with any questions. I look forward to talking with you.

Very truly yours,

William A. Weppner

Contain NO CBI

William A. Weppner, Ph.D
Director of Environmental, Health, Safety, and Regulatory Affairs
Specialty Materials Markets
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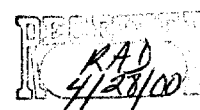
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Attachments to April 21, 2000 letter to C. Auer from W. Weppner (Radiolabel Oral Absorption and Intravenous Pharmacokinetic Studies in Rats)

3M Technical

1. Synthesis and Characterization of FC-95-¹⁴C, November 2, 1979.
2. Extent and Route of Excretion and Tissue Distribution of Total Carbon-14 in Rats after a Single Intravenous Dose of FC-95-¹⁴C, December 28, 1979.
3. Absorption of FC-95-¹⁴C in Rats after a Single Oral Dose, October 26, 1976
4. J. D. Johnson, et. al., Cholestyramine-Enhanced Fecal Elimination of Carbon-14 in Rats after Administration of Ammonium [¹⁴C]Perfluorooctanoate or Potassium [¹⁴C]Perfluorooctanesulfonate, Fundamental and Applied Toxicology 4, pages 972-976 (1984).



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Attachments to April 21, 2000 letter to C. Auer from W. Weppner (Dermal Absorption and Intravenous Pharmacokinetics in Rabbits)

3M Technical Reports

1. Single-Dose Intravenous Pharmacokinetic Study of T-6246 in Rabbits. 3M Environmental Laboratory Study # AMDT-042095.1
2. Single-Dose Dermal Absorption/Toxicity Study of T-6049 in Rabbits. 3M Environmental Laboratory Study # AMDT020895.1
3. Single-Dose Intravenous Pharmacokinetic Study of T-6049 in Rabbits. 3M Environmental Laboratory Study #AMDT-112294.1

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Attachments to April 21, 2000 letter to C. Auer from W. Weppner (Teratology Studies in Rats and Rabbits)

1. Rat Teratology Study T-3351 Final Report Dec 19, 1983, Hazelton Laboratories America Project #154-160.
2. December 7, 1983 Letter to Mr. William C. McCormick, III from E. Marshall Johnson, Ph.D., reviewing draft of above.
3. Oral Teratology Study of FC-95 in Rats, Riker Laboratory, Experiment # 068TR0008, December, 1980.
4. November 12, 1982, Letter to Franklin D. Griffith, Ph.D. from E. Marshall Johnson, Ph.D., reviewing the above.
5. Oral (Stomach Tube) Developmental Toxicity Study of PFOS in Rabbits, Study #418-012, January 11, 1999, Argus Laboratories.

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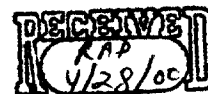
April 21, 2000



Attachments To April 21, 2000 Letter to C. Auer from W. Weppner
(Medical Surveillance and Epidemiology)

Final Reports

1. An Epidemiologic Investigation of Clinical Chemistries, Hematology and Hormones in Relation to Serum Levels of Perfluorooctanesulfonate in Male Fluorochemical Production Employees. [Included is a 3M report of medical surveillance data. Also included is a published paper from this 3M report.]
2. Fluorochemical Exposure (Serum) Assessment of (3M) Decatur Chemical and Film Plant Employees. [Included are a 3M study protocol and report.]
3. Mortality Study of Employees at 3M Plant in Decatur, Alabama [Included is a University of Minnesota final report.]
4. Determination of Serum Fluorochemical Levels in Sumitomo 3M Employees [Included are a 3M study protocol and final report.]
5. Analysis of Selected Decatur Employee Serum for Sulfonic and Carboxylic Fluorochemicals [Included is a 3M technical report.]
6. Fluorochemical Control Study [Included is a 3M report of medical surveillance data.]
7. Working Memorandum on Data Quality Assessment [Included is a Battelle Laboratory memorandum regarding the mean and range of perfluorooctanesulfonate sera sample data collected by 3M from current and historical human populations.]



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Attachments to April 21, 2000 letter to C. Auer from W. Weppner (Tissue Extraction and Analysis Methods)

1. 3M Environmental Laboratory Method. Extraction of Potassium Perfluorooctanesulfonate or Other Fluorochemical Compounds from Serum for Analysis Using HPLC-Electrospray/Mass Spectrometry. Method Number: ETS-8-4.1. Adoption Date: 03/01/99.
2. 3M Environmental Laboratory Method. Analysis of Potassium Perfluorooctanesulfonate or Other Fluorochemicals in Serum Extracts Using HPLC-Electrospray/Mass Spectrometry. Method Number: ETS-8-5.1. Adoption Date: 03/01/99.
3. 3M Environmental Laboratory Method. Extraction of Potassium Perfluorooctanesulfonate or Other Fluorochemical Compounds from Liver for Analysis Using HPLC-Electrospray/Mass Spectrometry. Method Number: ETS-8-6.0. Adoption Date: 07/22/99.
4. 3M Environmental Laboratory Method. Analysis of Potassium Perfluorooctanesulfonate or Other Fluorochemicals in Liver Extracts Using HPLC-Electrospray/Mass Spectrometry. Method Number: ETS-8-7.0. Adoption Date: 07/22/99.
5. 3M Environmental Laboratory Method. Extraction of Potassium Perfluorooctanesulfonate or Other Fluorochemical Compounds from Urine for Analysis Using HPLC-Electrospray/Mass Spectrometry. Method Number: ETS-8-96.0. Adoption Date: 07/28/99.
6. 3M Environmental Laboratory Method. Analysis of Potassium Perfluorooctanesulfonate or Other Fluorochemicals in Urine Extracts Using HPLC-Electrospray/Mass Spectrometry. Method Number: ETS-8-97.0. Adoption Date: 07/28/99.

Study Protocols/Proposals of Ongoing Research

1. Identification of Fluorochemicals in Sera of Children in the United States. [Included is a 3M study protocol. Study is on-going. Final report due January 1, 2001]
2. Serum fluorochemical trends of out-of-county residents in CLUE I (1974) and Clue II (1989) epidemiologic investigations. [Included is a Johns Hopkins University study protocol. Study is on-going. Joint 3M/Johns Hopkins University final report is due January 1, 2001.]
3. Identification of Fluorochemicals in Human Tissue. [Included is 3M study protocol. Study is on-going. Final report is due January 1, 2001.]
4. An Epidemiologic Analysis of the Inpatient and Outpatient Claims Event and Episode Experience of 3M Decatur Employees, 1993-1998. [Included is a 3M study protocol. The study is on-going. Final report is due September 15, 2000.]
5. Determination of Serum Elimination Half-Lives of Ammonium Perfluorooctanoate, Perfluorooctane Sulfonic Acid, Perfluorohexane Sulfonic Acid and Total Organic Fluorine in Decatur Chemical Plant Retirees. [Included is a 3M study protocol. The study is on-going. Final report is due June 1, 2004. Interim draft reports will be issued.]

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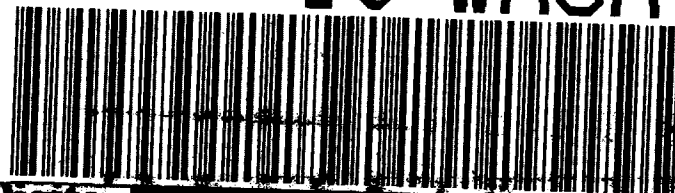
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