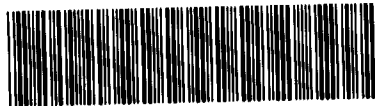


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May 15, 2000



FYI-00-001378

MAY 25 AM 11:10

3M

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

MR 36091

Contain NO CBI

RE: Supplemental Information on Perfluorooctane Sulfonates

Dear Charlie:

3M is enclosing additional information on perfluorooctane sulfonates to supplement our submittal dated May 4, 2000. The supplemental information consists of the following:

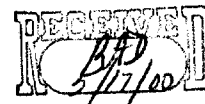
1. Four pages of executive summaries that were included in the May 4, 2000 submittal as introductions to the environmental science areas. However, our cover letter to you of May 4 also indicated that we would provide copies as part of the cover letter. We inadvertently failed to include them as part of the attachments to the cover letter, and do so now.
2. A summary entitled "26-Week Capsule Toxicity Study with Perfluorooctanesulfonic Acid Potassium Salt (PFOS) in Cynomolgus Monkeys, Current Summary as of May 4, 2000." It is our understanding that this summary was hand-delivered to you by Dr. Larry Zobel at a recent meeting between 3M and EPA, but we supply another copy to complete the filing.
3. The cover page to the resubmittal of confidential information previously submitted on May 4. We inadvertently failed to provide both a sanitized and confidential copy, and Terry O'Brien asked that we resubmit this information to the Document Processing Center.

Please do not hesitate to contact me at 651-733-6374 should you have any questions.

Very truly yours,

William A. Weppner

William A. Weppner, Ph.D
Director of Environmental, Health, Safety
& Regulatory Affairs
Specialty Materials Markets
3M Center, Bldg 236-1B-10
St. Paul, MN 55144-1000



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PHYSICAL - CHEMICAL PROPERTIES

A Robust Summary, Final Report, and Protocol on the physical-chemical properties of perfluorooctanesulfonate are included for each of the following parameters:

<u>PARAMETER</u>	<u>DATE OF REPORT</u>	<u>RESULTS</u>
Melting Point/Melting Point Range	2/24/99	$\geq 400^{\circ}\text{C}$
Vapor Pressure	5/5/99	$3.31 \times 10^{-4} \text{P@}20^{\circ}\text{C}$
n-Octanol/Water Partition Coefficient	2/11/00	Not calculable; three phases
Air-Water Partition Coefficient	3/19/00	$0(<2 \times 10^{-6})$
Solubility in pure water	5/3/99	570mg/l
Solubility Measurements on FC-95	2/6/81	1080mg/l

The data presented in the study "Solubility Measurements on FC-95," was determined by indirect measurement, not by actual analysis. Therefore, the data is not reliable.

Please note that the March 1, 2000 submittal to EPA entitled "Sulfonated Perfluorochemicals in the Environment Sources, Dispersion, Fate and Effects" included solubility data on water other than pure (*i.e.*, fresh water; filtered sea water; unfiltered sea water). These data were developed, however, in support of other studies and not produced using GLP Standards. For this reason, Robust Summaries, Final Reports, or protocols for this specific data are not being provided.

ENVIRONMENTAL FATE AND TRANSPORT

This section presents information and test results from abiotic, and biotic degradation and soil adsorption studies. Degradation studies include hydrolysis, photolysis, and biodegradation. Much of this work is in progress with final reports scheduled for the June to August, 2000 timeframe.

As these studies progress, there are certain key findings that can be presented as preliminary results:

1. There has been no indication that perfluorooctanesulfonate undergoes any degradation from hydrolysis, photolysis, or biodegradation mechanisms.
2. In all hydrolysis and photolysis studies, perfluorooctanesulfonate has not been detected as a degradation product in any conclusive experiment. This preliminary finding calls into question the assumption of expected degradation of other fluorochemicals to perfluorooctanesulfonate.
3. In the studies focused on hydrolysis of fluorochemical polymers that form the structure of the specific industrial and consumer products, it has been determined that these materials are relatively stable in the environment. For example, the following half-lives are estimated for various polymers:

<u>POLYMER</u>	<u>HALF-LIFE</u>
Acrylate and ester	1-5 years
Polyethylene glycol based	3-50 years
Urethane	>500 years

For hydrolysis to occur, polymers must be subjected to an aqueous environment, which is not expected to occur in a municipal or industrial landfill.

4. Relative to photolysis, the current data suggests a hypothesis that these materials will photolyze to carboxylate structures. These structures have much different properties than sulfonates in that they are much less bioaccumulative in ecological species.

Additional discussion of these results and ongoing studies will be presented in subsequent submissions and reports.

ECOTOXICITY ELEMENTS

This section presents information and test results from a series of ecotoxicity studies on perfluorooctanesulfonates. The information is presented as Robust Summaries, Final Report and Protocol for each ecotoxicity element.

The studies performed during 1999 and in early 2000 were carried out using GLP Standards. In contrast, ecotoxicity studies performed during the period 1974 to 1998 were conducted using protocols and analytical methodologies available at the time of the study. In addition, in these older tests, the sulfonated perfluorochemical products were variable mixtures and contained more impurities. Several tests were hampered by the insolubility of the perfluorochemical and results are expressed as "greater than" the measured solubility. Therefore, the data presented in these historical reports may not be reliable.

ENVIRONMENTAL MONITORING:
PART ONE -- MULTI-CITY STUDY

The multi-city study was designed to obtain preliminary data about dispersion of fluorochemicals in the environment, uptake into foods and presence in drinking water to understand the potential sources of human and environmental exposures that might result from this type of dispersion. The multi-city study paired a city having manufacturing or commercial use of fluorochemical products based on customer sales with a city that does not. Initially six cities, (three pairs) are being examined. The study may be expanded depending on further results.

The multi-city study will yield environmental distribution data as well as data on potential sources of human exposure. The cities were selected to represent urban locations with various levels of fluorochemical releases and various types of municipal water supplies. The samples to be obtained, where possible, include: urban air, surface water column and surface microlayer, sediment, river fish, drinking water intake, treated drinking water, tap water, the influent to and effluent from publicly-owned waste treatment works, sludge, and municipal landfill leachate. Additionally, a "market basket" of several food products will be sampled. These include: beef, pork, chicken, hot dogs, catfish, eggs, milk, bread, green beans, apples from grocery stores and, if possible, produce from local farmers' markets.

The attached material data provides more detail on the design and structure of the study and represents the first results from the multi-city study. Included are reports on the quality assurance plan and field sampling procedures used and the results of the drinking water samples taken from the six cities. The results indicate that drinking water in four cities (Decatur, Alabama; Cleveland, Tennessee; Mobile, Alabama; and Port St. Lucie, Florida) did not contain detectable levels of fluorochemicals. Only two cities (Columbus, Georgia, and Pensacola, Florida) contained detectable levels of sulfonated fluorochemicals in the drinking water. The results show that the levels are in the range of 40-60 parts per trillion of perfluorooctane sulfonate. Only one city, Columbus, Georgia, showed very low detectable levels of perfluorooctanoate.

Also included is a copy of a draft "lifetime" drinking water health advisory developed for PFOS. This advisory reflects a very conservative approach based on application of "safety factors." The advisory level of 1 part per billion should not be misconstrued as threshold for danger or concern, but only a reference point based on application of conservative methods and the information available to date. A comparison of the drinking water data from the multi-city study indicates that there are two orders of magnitude of safety between the draft drinking water advisory and the results from these two cities in the multi-city study.

ENVIRONMENTAL MONITORING: PART TWO – BIOSPHERE SAMPLING AND ANALYSIS

A plan to assess potential environmental exposure to perfluorooctanesulfonate and other fluorochemical substances has been developed by 3M and outside experts. One component of this plan involves characterization of the geographic distribution of fluorochemicals in biotic and abiotic receptors. Two studies are in progress, one focused in the vicinity of the 3M Decatur, Alabama manufacturing facility, and the other a much more comprehensive global biosphere monitoring program. The preliminary results obtained to date have been reported in the 3M Environmental White Paper entitled "Sulfonated Perfluorochemicals in the Environment: Sources, Dispersion, Fate and Effects."

The study in the Decatur, Alabama area is being designed to understand the impact, if any, of production operations in the local environment. Samples of the groundwater, surface water, sediments and fish and bird species will be collected in May and June, 2000 for analyses. This data will be used to evaluate the environmental presence of fluorochemicals and to assess the potential of any effects using ecotoxicological test results.

The Biosphere monitoring program was designed in consultation with Dr. John Geisy of Michigan State University. This plan is being viewed as an iterative process to assess global distribution of fluorochemicals. As results are obtained from the global environment, the plan is to concentrate on those areas where fluorochemicals are detected in samples and focus on additional sampling and analyses in those specific locations.

Initially, samples of tissues and blood plasma are being collected from archived specimens covering different species and locations. Areas of focus include North America (Great Lakes and coastal marine locations), the arctic region, and Europe. Species to be studied include lake trout, walleye, salmon, catfish, and brown trout; cormorants, eagles and albatross; mussels and shellfish; marine mammals; and other species. This sampling plan is in progress and as data is obtained and reports generated, additional submissions will be made to EPA.

Included in this section are the following documents:

1. LCMSMS Analysis of Extracts reported in: "Preliminary Report Analysis of Perfluorinated Compounds in Environmental Samples" by P. Jones and K. Kannan - 4/7/99
2. Final Laboratory 3M Reports on Analysis of Fluorochemicals in Wild Bird Livers - 4/28/99
3. Screening of PFOS levels in Eagle and Albatross - 5/8/98

26-Week Capsule Toxicity Study with Perfluorooctanesulfonic Acid Potassium Salt (PFOS) in Cynomolgus Monkeys

Current Summary as of May 4, 2000

The purpose of this study was to identify the earliest clinically measurable biological response from repeated daily exposure to potassium perfluorooctane sulfonate (PFOS) and to correlate this response to serum concentrations for purposes of risk assessment and medical monitoring of exposed populations. Groups of male and female Cynomolgus monkeys received daily doses of 0 (six per sex), 0.03 (four per sex), 0.15 (six per sex), or 0.75 (six per sex) mg/kg/day potassium perfluorooctane sulfonate for 26 weeks by capsule via gastric intubation. Two males and two females in each of the 0, 0.15 and 0.75 mg/kg/day dosed groups were followed for one year after cessation of dosing to observe depuration of compound and reversibility of effects. There were no recovery animals in the 0.03 mg/kg/day dose group. This report covers the 26 weeks of dosing. A separate report will detail the findings from 52 weeks of recovery. Effects occurring in the 0.75 mg/kg/day dose group which are believed to be compound related include: 1) severe illness of two males which died or were sacrificed *in extremis* within the last month of treatment; 2) lower body weight in males and females; 3) increased liver weight and hepatocellular hypertrophy and vacuolation in animals; 4) lowering of serum cholesterol in correlation to increasing serum PFOS levels during treatment; 5) lowered triiodothyronine (T3) values in both males and females; 6) lowered estradiol (E2) levels in males. No significant compound-related effects were observed in monkeys treated with 0.03 or 0.15 mg/kg/day over 26 weeks. Serum PFOS values increased linearly to an average of 18 and 90 in the 0.03 and 0.15 mg/kg/day dose groups, respectively. The increase in serum PFOS in the 0.75 mg/kg/day dose group was not linear during the dosing period and reached an average of 215 ppm after 26 weeks of dosing. Liver PFOS levels averaged 25, 80 and 415 ppm for 0.03, 0.15, and 0.75 mg/kg/day dose groups, respectively. Cholesterol values returned to pre-dose levels within 36 days of recovery, without correlation to serum PFOS. Serum PFOS had an apparent elimination half-life of 275 and 128 days over the first six-months of recovery in the 0.15 and 0.75 mg/kg/day dose groups, respectively. The decrease in total serum cholesterol observed in high-dose animals was confirmed as the earliest measurable clinical response. The lowering of total serum cholesterol occurred only at serum PFOS concentrations greater than 100 ppm. The biological responses observed in this study are consistent with prior rodent and monkey studies with the exception that hepatocellular peroxisome proliferation, as observed in rodents, was not observed in this study. Health effects have not been observed from years of medical monitoring of 3M chemical workers with occupational exposure resulting in average serum concentrations of approximately one to two ppm, and generally less than six ppm (Olsen et al., JOEM Sept., 1999). Therefore, non-occupationally exposed populations with pooled average serum PFOS concentrations that are one to two orders of magnitude lower than average worker serum concentrations (3M, "Perfluorooctane Sulfonate: Current Summary of Human Sera, Health and Toxicology Data", January 21, 1999) have a margin of safety of 10^3 to 10^4 with respect to the first clinically measurable biological response to perfluorooctane sulfonate exposure, cholesterol lowering.

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May 15, 2000

Document Processing Center (Mail Code 7407)
Information Management Division
Office of Pollution Prevention and Toxics
United States Environmental Protection Agency
401 M Street, SW
Room 699 East Tower
Washington, D. C. 20460
Attn: FYI

Dear Sir/Madam:

This submission is being made per the phone conversation between Terry O'Brien (EPA) and Dan Hakes (3M) on May 10, 2000. Terry requested a non-confidential version of a specific toxicological study. I would like to confirm that portions of the "Exploratory 28-Day Oral Toxicity Study with (various fluorochemicals) By Daily Gavage in the Rat Followed by a 14/28-Day Recovery Period", plus the associated laboratory report submitted to Dr. Charles Auer on May 4, 2000 is considered TSCA Confidential Business Information.

Attached for your review is a new copy of the above mentioned study to be included with the submittal on perfluorooctane sulfonates made by 3M to Dr. Charles Auer dated May 4, 2000. Attached to this letter is a complete non-confidential report with the TSCA Confidential Business Information redacted. In a separate envelope is the same report with the TSCA CBI included and highlighted.

Very truly yours,

A handwritten signature in cursive script that reads "John L. Butenhoff".

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