3M Specialty Materials

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3M

VIA OVERNIGHT DELIVERY

December 22, 2000

Document Processing Center (7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460

Attention: For Your Information Docket - Docket No. AR-226

Re: Information on Perfluorooctane Sulfonates and Related Compounds

Dear Sir or Madam:

This continues 3M's voluntary submissions of data on perfluorooctane sulfonates and related compounds, as part of our ongoing dialog with EPA regarding fluorochemistry.

Contents of this Submission

In this submission, we are enclosing some new information and some older documents that have only recently been located. All of the information in this submission relates to health effects research. We expect to provide an environmental submission, along with additional new health effects research information, within the next few months.

Analytical Data for Previously Submitted Studies

- This submission includes recent final analytical reports providing liver and serum values for the PFOS monkey study and the N-ethyl FOSE two-generation rat study. The PFOS monkey study report updates an interim analytical report submitted May 4, 2000. The analytical data for the N-ethyl FOSE two-generation study had not previously been submitted. As indicated in the draft Initial Assessment Report, the laboratory is continuing to update the serum and liver values for various studies. Additional revised values for other studies will be forthcoming in future submissions.

- This submission also includes analytical values on liver and serum from 1978/79 monkey studies with PFOS and N-ethyl FOSE. We have only recently located these old analytical reports.

Additional Copies of Information Submitted to TSCA Section 8(e) Docket

- For convenience, we have included in this package copies of three recent submissions under TSCA Section 8(e).

  - The first relates to an update of the mortality study at the Decatur plant where fluorochemicals are produced, showing a statistically significant excess of urinary bladder cancer (based on three cases). Based on all of the available toxicology information, we do not believe it is biologically plausible that the observed excess relates to fluorochemical exposure. We are continuing to investigate this finding, and as indicated in the Section 8(e) letter, the report is still in preparation.

  - The second Section 8(e) submission reproduced here for convenience pertains to findings from the 104-week bioassay using N-ethyl FOSE. That study resulted in a statistically significant excess of benign hepatocellular adenomas, and one hepatocellular carcinoma, in female rats only, and only at the high dose. The final report on that study will be delayed. Given the recent finding of an excess of bladder cancer in the Decatur mortality study, we have asked the laboratory to review urinary bladder tissue of all animals in the study. The laboratory had already examined the urinary bladders of high-dose and control animals, with no findings of note. However, we have asked for the additional work to ensure that there is no abnormal pathology present in the urinary bladders at any dose. We expect this work may delay issuance of the final report on the chronic N-ethyl FOSE study by several months. We have therefore included the Section 8(e) letter containing the significant information from the chronic bioassay in this package. (We have not yet received the results of the chronic PFOS study. We have made the same request regarding additional tissue examination in that study, and accordingly, also expect that study to be delayed pending completion of additional work.)

  - We have also included a report on a 13-week dietary study of N-Methyl Perfluorooctanesulfonamido Ethanol (N-Methyl FOSE) submitted to the TSCA docket by letter dated July 24, 2000.

Mixtures

- Our series of data submissions have provided to you studies administering specified fluorochemicals (13 chemicals, counting PFOS acid and its various salts as one, were covered in the document submissions). We also provided a submission in June 2000 regarding mixtures in which PFOS is present as an intentional ingredient. That mixture submission essentially covered our AFFF product, known as Lightwater®, which contains small amounts of PFOS. As I discussed in a recent telephone conversation with Dr. Oscar Hernandez of EPA, the utility of these mixture studies for toxicological evaluation and risk assessment is limited. Accordingly, although 3M has located a few additional such studies, we agreed that these need not be submitted.

- Dermal or intravenous absorption studies that administered a covered fluorochemical to test animals have already been supplied in our previous submissions. We note that there also exist studies that administered a mixture to the test species, and then measured the presence of a covered chemical such as PFOS in the animal. The data from these studies is of limited utility, however. The studies were intended to be only a screening-level survey of exposure potential. They do not indicate the rate of absorption or whether the presence of any fluorochemical resulted from absorption versus metabolism. Many of the products administered to the animals were experimental rather than commercial products, and in some cases only limited information is available as to the composition of the test material. As with the AFFF studies on mixtures, and particularly given the limited usefulness of these mixture studies, we are not providing copies of these studies.

Compact Discs

We have previously provided you with a compact disc containing our April and early May submissions. We are now enclosing two additional CDs:

- Disc 2 covers the submissions dated May 23, 2000 through June 2000.

- Disc 3 covers the August submission and this submission.

Thus, you will now have all of the data submissions in electronic format. Note that each of the document submissions may include information on multiple chemicals.

As with the first CD, the enclosed CDs include a copy of the cover letter and index for each submission, followed by the data. Also as with the first CD, these electronic documents are for read-only purposes and are not to be

modified. 3M will maintain paper copies, and in the event of any discrepancy, the 3M paper copies will be considered controlling. The CDs include only the public version of any confidential information; EPA should refer to the paper copies for any information submitted under claim of confidentiality.

* * *

We will continue to provide information on a regular basis as it becomes available. I will be retiring from 3M effective January 10, 2001. You may feel free to contact me until then, or after that, please contact my successor Michael Santoro (at the same phone number shown below) with any questions.

Very truly yours,

William A. Weppner

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cc: Dr. Charles Auer
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(with index but without other enclosures)

ATTACHMENT TO LETTER OF DECEMBER 22, 2000
SUPPLEMENTAL SUBMISSION

TOXICOLOGY AND MEDICAL SURVEILLANCE

PFOS	**Perfluorooctane sulfonate**

Medical Surveillance

1. Letter submitted under TSCA Section 8(e) regarding update of Decatur plant mortality study, December 15, 2000.

Repeat Dose

1. Analytical Laboratory Report, September 19, 2000, "26-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (T-6295) in Cynomolgus Monkeys, Determination of the Presence and Concentration of Perfluorooctanesulfonate (PFOS) in Liver and Serum Samples," to accompany Covance Laboratories Inc., Study No. 6329-223, 3M Medical Department Study No. T-6295.7, Report No. FACT TOX-030 [unaudited draft of in-life report and interim report of preliminary analytical data were submitted May 4, 2000].

   [Note: This report contains revised analytical data updating that in the October 2000 draft Initial Assessment Report. The draft Initial Assessment Report contained data available as of July 2000 and noted that revisions would be forthcoming.]

2. Technical Report Summary and Central Analytical Laboratory Report No. 6967, providing analytical data for Ninety-Day Subacute Rhesus Monkey Toxicity Study, with Fluorad® Fluorochemical Surfactant FC-95, International Research and Development Corporation, Project No. 137-092, 3M Reference No. T-3351, August 4, 1978 [final in-life report was submitted May 4, 2000].

ATTACHMENT TO LETTER OF DECEMBER 22, 2000
SUPPLEMENTAL SUBMISSION

N-EtFOSE alcohol	**N-ethyl perfluorooctane sulfonamidoethanol**

Genotoxicity

1. Final Report, L5178Y TK +/- Mouse Lymphoma Forward Mutation Assay with a Confirmatory Assay with N-EtFOSE T-6316, Covance Laboratories, Inc., Study No. 20785-0-431 ICH, 3M Reference No. T-6316.12, September 5, 2000

   [Note: This is a repeat of Final Report, Evaluation of the Mutagenic Activity of T-6906 in an In Vitro Mammalian Cell Gene Mutation Test with L5178Y Mouse Lymphoma Cells, NOTOX Study No. 223458, 3M Reference No. FM-3923, December 22, 1998, submitted May 18, 2000, with a letter from Covance Laboratories (reviewing the NOTOX study and concluding it was technically inadequate and should be repeated)].

Repeat Dose

1. Letter submitted under TSCA Section 8(e) regarding results of 104-week chronic study, December 4, 2000.
2. Technical Report Summary and Central Analytical Laboratory Report No. 6995, providing analytical data to accompany Ninety Day Subacute Rhesus Monkey Toxicity Study on FM-3422, International Research and Development Corporation, Study No. 137-088, August 16, 1978 [final in-life report submitted May 18, 2000].

Teratology & Reproductive

1. Combined Oral (Gavage) Fertility, Developmental and Perinatal/Postnatal Reproduction Toxicity Study of N-EtFOSE in Rats, 3M Reference No. T-6316.5, Argus Protocol No. 418-009, FACT-TOX-013, June 30, 1999 ["two-generation study" previously reported to TSCA 8e docket]
   a. Report Amendment 1, October 12, 2000, amending figure.
   b. Analytical Laboratory Report, October 9, 2000, "Determination of the Presence and Concentration of PFOS, M556, PFOSAA, and PFOSA in the Liver and PFOS, M556, PFOSA, and EtFOSE-OH in the Sera of Crl:CD®BR VAF/Plus® Rats Exposed to Et-FOSE-OH"

N-MeFOSE alcohol	**N-methyl perfluorooctane sulfonamido ethanol**

Repeat Dose

1. Covance Laboratory, 13-Week Dietary Study of N-Methyl Perfluorooctansulfonamide Ethanol (N-MeFOSE) in Rats, and 4-week Range-Finding Study, 3M Reference No. T-6314, along with letter dated July 24, 2000 submitting reports to TSCA Section 8(e) docket.

PFOA	**Perfluorooctanoic acid**

Genotoxicity

1. Report to 3M Company, Reverse Mutation Studies with T-1485 in Five Salmonella Strains and One Saccharomyces Strain, Industrial Bio-Test Laboratories, Inc., IBT No. 8540-09238, August 10, 1976.

Published Literature (Bibliography Only)

1. Olsen, GW, Burris, JM, Burlew, MM, and Mandel, JH, Plasma Cholecystokinin and Hepatic Enzymes, Cholesterol and Lipoproteins in Ammonium Perfluorooctanoate Production Workers, *Drug and Chemical Toxicology* 23(4): 603-620 (2000).
2. Reo, NV, Adinehzadeh, NMR Spectroscopic Analyses of Liver Phosphatidylcholine and Phosphatidylethamine Biosynthesis in Rats Exposed to Peroxisome Proliferators - A Class of Nongenotoxic Hepatocarcinogens, *Toxicology and Applied Pharmacology* 2000; 164: 113-126.