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Document Processing Center (7407)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460
Attn: TSCA Section 8(e) Coordinator

Dear Section 8(e) Docket Coordinator:

Re: TSCA 8(e) Supplemental Notice on Sulfonate-based Fluorochemicals

With this letter, 3M is providing final reports and other supplemental information related to previous TSCA Section 8(e) notifications. Many of the enclosed items are analytical reports providing blood serum and liver levels of test materials for which the in-life report referring to administered doses has already been submitted to the 8(e) docket. In other cases where the 8(e) notification consisted of preliminary data, we are submitting a final study report.

All of the enclosed items are already in EPA's possession and available in TSCA Docket AR-226. We believe, however, that placing these items in the 8(e) docket may allow for more convenient access to information directly related to previous 8(e) notifications by 3M.

The table below lists the enclosed items and references the study or data which already has been the subject of an 8(e) notification by 3M:

Attached Submission	Related Study/Data Already Filed Under 8(e)
1. Amended Analytical Study, 2(N-Ethylperfluorooctane sulfonamido)-ethanol in Two Generation Rat Reproduction, Determination of the Presence and Concentration of PFOS, M556, PFOSAA, and PFOSA in the Liver and PFOS, M556, PFOSAA, PFOSA and EtFOSE-OH in the Sera of Crl:CDBR VAF/Plus Rats Exposed to EtFOSE-OH, 3M Reference No. T-6316.5, Analytical Report TOX-013, LRN-U2095, June 11, 2001.	Combined Oral (Gavage) Fertility, Developmental and Perinatal/Postnatal Reproduction Toxicity Study of N-EtFOSE in Rats, 3M Reference No. T-6316.5, June 30, 1999, full report submitted February 15, 2000 to supplement earlier filing

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Exhibit
2789
State of Minnesota v. 3M Co.,
Court File No. 27-CV-10-28862

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2789.0001

Attached Submission	Related Study/Data Already Filed Under 8(e)
2. Analytical Laboratory Report, Determination of the Presence and Concentration of Potassium Perfluorooctanesulfonate (CAS Number: 2759-39-3) in the Serum and Liver of Sprague-Dawley® Rats Exposed to PFOS via Gavage, Laboratory Report No. U2006, Requestor Project No. 3M TOX 6295.9, October 27, 1999. 3. Report Amendment 1, Combined Oral (Gavage) Fertility, Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFOS in Rats, Argus Research Laboratories, Inc., Protocol 418-008, Sponsor's Study No. 6295.9, April 13, 2000.	Combined Oral (Gavage) Fertility, Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFOS in Rats, Argus Research Laboratories, Inc., Sponsor's Study No. 6295.9, June 10, 1999, full report submitted February 15, 2000 supplementing earlier filing
4. Analytical Report, Determination of the Presence and Concentration of Perfluorooctanesulfonate, Perfluorooctanesulfonylamide, M556, and M570 in the Liver and Sera Samples, 3M Environmental Laboratory Ref. No. U2636, TOX-028, February 23, 2001	13-Week Dietary Study of N-Methyl Perfluorooctanesulfonamido Ethanol (N-MeFOSE) in Rats, 3M Ref. No. T-6314.1, Covance Study No. 6329-225, dated June 30, 2000, Section 8(e) filing July 24, 2000
5. Analytical Laboratory Report, Determination of the Concentration of PFOS, PFOSA, PFOSAA, and EtFOSE-OH in the Sera and Liver of Crl:CDBR VAF/Plus Rats Exposed to N-EtFOSE, 3M Environmental Laboratory Report No. TOX-098, Laboratory Request No. U2402, 3M Ref. No. T-6316.7, February 6, 2001.	Final Report, Oral (Gavage) Developmental Toxicity Study of 2(N-Ethylperfluorooctanesulfonamido)-ethanol in Rats, 3M Reference No. T-6316.7, December 17, 1998, submitted to Section 8(e) docket per letter of August 21, 2000
6. Analytical Laboratory Report on the Determination of the Presence and Concentration of Potassium Perfluorooctanesulfonate (PFOS) or another metabolite of 2(N-ethylperfluorooctanesulfonamido)-ethanol (N-EtFOSE) in Liver and Serum Specimens, 3M Environmental Laboratory Report No. TOX-097, Laboratory Request No. U2452, 3M Ref. No. T-6316.8, February 8, 2001	Final Report, Oral (Stomach Tube) Developmental Toxicity Study of N-EtFOSE in Rabbits, 3M Reference No. T-6316.8, January 11, 1999, submitted to Section 8(e) docket per letter of August 21, 2000
7. Final Report, Alexander, B., Mortality Studies of Workers Employed at the 3M Decatur Facility, University of Minnesota, April 26, 2001.	Preliminary data submitted to Section 8(e) docket in letter of December 15, 2000

Attached Submission	Related Study/Data Already Filed Under 8(e)
8. Final Report, Acute Oral Toxicity Screen with T-3290CoC in Albino Rats, Safety Evaluation Laboratory, Riker Laboratories, Inc., Project No. 0882AR0362, 3M Reference No. T-3290 (40 % K^+PFOSAA in 3 % EtOH, 17 % IPA and 40 % H_20, L-6778, F-6873, Lot 501), November 5, 1982 *[Bibliography entry in Docket AR-226, final report was to be moved to TSCA 8(e) docket]*	Acute Oral Toxicity Screen with T-3290CoC in Albino Rats, Safety Evaluation Laboratory, Riker Laboratories, Inc., Project No. 0882AR0362, 3M Reference No. T-3290 (40 % K^+PFOSAA in 3 % EtOH, 17 % IPA and 40 % H_20, L-6778, F-6873, Lot 501), November 5, 1982, submitted to Section 8(e) docket in August 21, 2000 self-audit letter (which erroneously refers to rabbits rather than rats)
9. Giesy, J.P., and K. Kannan, Accumulation of Perfluorooctanesulfonate and Related Fluorochemicals in Fish Tissue, Michigan State University, June 20, 2001. 10. Giesy, J.P., and K. Kannan, Accumulation of Perfluorooctanesulfonate and Related Fluorochemicals in Mink and River Otters, Michigan State University, June 20, 2001. 11. Giesy, J.P., and K. Kannan, Perfluorooctanesulfonate and Related Fluorochemicals in Oyster, Crassostrea Virginica, From the Gulf of Mexico and Chesapeake Bay, Michigan State University, June 20, 2001. 12. Giesy, J.P. and K. Kannan, Perfluorooctanesulfonate and Related Fluorochemicals in Fish-Eating Water Birds, Michigan State University, June 20, 2001. 13. Giesy, J.P. and K. Kannan, Accumulation of Perfluorooctanesulfonate and Related Fluorochemicals in Marine Mammals, Michigan State University, June 20, 2001.	Preliminary data submitted to Section 8(e) docket May 26, 1999

If you have any questions about this submission, please contact me at (651)737-4795.

Sincerely,

Georjean Adams

Georjean Adams
Manager, 3M Corporate Product Responsibility

Enclosures

L-6778, F-6873

MR 51674

Acute Oral Toxicity Screen with T-3290CoC in Albino Rats

Experiment No.: 0882AR0362

Conducted At: Safety Evaluation Laboratory
Riker Laboratories, Inc.
St. Paul, Minnesota

Dates Conducted: July 30, 1982 to August 27, 1982

Conducted By: H. S. Rhodes 10/28/82
H. S. Rhodes, Jr. Laboratory Technician, Acute Toxicology — Date

8EHQ-80-373

D. M. Markoe, Jr. 10/28/82
D. M. Markoe, Jr., BS, Toxicologist, Study Director — Date

Reviewed By: Karen D O'Malley 11/5/82
K. D. O'Malley, BS, Senior Toxicologist, Acute Toxicology — Date

dc: M. T. Case
K. L. Ebbens
F. D. Griffith
W. C. McCormick

Confi[illegible]

Summary

An acute oral toxicity screen with T-3290CoC was conducted from July 30, 1982 to August 27, 1982 at Riker Laboratories, Inc., St. Paul, Minnesota using male and female albino rats ranging in body weight from 209-269 grams. The test article was administered by gastric intubation at a dose level equivalent to 200 mg/kg and 1250 mg/kg body weight with 0/10 mortalities noted at the 200 mg/kg dose level and 9/10 mortalities noted at the 1250 mg/kg dose level. The untoward behavioral reactions which occurred during the 28 day observation period at the 200 mg/kg dose level consisted of hypoactivity from 60-120 minutes post dose administration. The 1250 mg/kg dose level exhibited hypoactivity, ataxia, diarrhea and, in the females, unkempt appearance. Recovery was generally precluded by death. Body weight gains were noted in all animals which survived the study. Necropsies performed at termination of the study revealed no visible lesions, however, autolysis precluded evaluation of three 1250 mg/kg dose level animals which died prior to the end of the study. The approximate oral LD50 of T-3290CoC is greater than 200 mg/kg and less than 1250 mg/kg in fasted male and female albino rats.

Introduction

The objective of this study was to approximate the acute oral LD50 of T-3290CoC in fasted albino rats. This study was conducted for research and development purposes and is, therefore, not regulated by the Food and Drug Administration's Good Laboratory Practice Regulation of 1978, although the standard operating procedures of this laboratory adhere to the general principles of this regulation. The raw data generated by the Study Director and the final report are stored in the conducting laboratory's archives.

Method and Results

Young albino rats[a] were used in this test. All animals were held under quarantine for several days prior to testing with only animals which appeared to be in good health and suitable as test animals at the initiation of the study used. The rats were housed in suspended, wire-mesh cages in temperature and humidity controlled rooms and permitted a standard laboratory diet[b] plus water ad libitum except during the 16-20 hour period immediately prior to gastric intubation when food was withheld.

The rats were administered the test material[c] at 200 mg/kg and 1250 mg/kg body weight. All doses were administered undiluted directly into the stomachs of the rats using a hypodermic syringe equipped with a ball-tipped intubating needle[d].

After gastric administration of the test article, the rats were returned to their cages and observed for the following 28 days. Initial, 14 day and final body weights, mortalities (Table 1) and adverse reactions (Table 1) were recorded. A necropsy was conducted on all animals that died during the study as well as those euthanatized and the end of the 28 day observation period (Table 1). The protocol, principal personnel involved in the study, composition characteristics and Quality Assurance statement are contained in Appendices I - IV.

[a] King Labs, Oregon, WI
[b] Ralston Purina Laboratory Chow, Ralston Purina, St. Louis, MO
[c] The test article is 40% solids and was dosed at 200 mg/kg and 1250 mg/kg of solids which is equivalent to an undiluted dose of 500 mg/kg and 3125 mg/kg "as is", respectively.
[d] Popper and Sons, New Hyde Park, NY

TABLE 1

ACUTE ORAL TOXICITY SCREEN - ALBINO RATS

with T-3290CoC

Mortality, Necropsy, Adverse Reactions and Body Weight Data

Dose [a] (mg/kg)	Sex	Animal Number	Individual Body Weights (g) Test Day Number: 0	14	28	Number Dead / Number Tested	Percent Dead
200	M	2R3587	253	293	328	0/5	0
		2R3588	251	306	351		
		2R3589	268	328	369		
		2R3590	263	309	346		
		2R3591	262	310	369		
200	F	2R3607	225	263	269	0/5	0
		2R3608	216	263	260		
		2R3609	219	236	252		
		2R3610	222	241	257		
		2R3611	219	235	249		
1250	M	2R3592	265	(Day 7)		4/5	80
		2R3593	260	(Day 6)			
		2R3594	263	(Day 5)			
		2R3595	269	303	367		
		2R3596	262	(Day 6)			
1250	F	2R3612	217	(Day 5)		5/5	100
		2R3613	222	(Day 4)			
		2R3614	216	(Day 5)			
		2R3615	214	(Day 5)			
		2R3616	209	(Day 3)			

[a] The test article was administered undiluted, however, the dose represents mgs of solids, of which the test article consists of 40% solids.

The acute oral LD50 is greater than 200 mg/kg and less than 1250 mg/kg in fasted male and female rats.

Note: Figures in parenthesis indicate time of death.

Necropsy

Necropsies performed upon termination revealed no visible lesions at the 200 mg/kg dose level. The 1250 mg/kg dose level produced no visible lesions upon necropsy, however, autolysis precluded evaluation of three animals.

TABLE 2

ACUTE ORAL TOXICITY SCREEN - ALBINO RATS

with T-3290CoC

Summary of Reactions

Dose mg/kg	Sex	Reactions	Observation Periods: Number Affected/Number Dosed — Minutes: 1-30	60	120	Days: 1	2	3	4	5	6	7	8	9	10	11	12	13	14*
200	M	Hypoactivity		5/5	5/5	0/5													
200	F	Hypoactivity		5/5	5/5	0/5													
1250	M	Hypoactivity		5/5	0/5	5/5	5/5	5/5	5/5	4/4	3/3	1/1	1/1	1/1	1/1	0/1			
		Ataxia			5/5	0/5					1/3	0/1							
		Diarrhea				4/5	2/5	0/5											
1250	F	Hypoactivity		5/5	0/5	5/5	5/5	4/4	3/3	0/0									
		Ataxia			5/5	0/5													
		Diarrhea			1/5	5/5	2/5	4/4	2/3	0/0									
		Unkempt						4/4	3/3	0/0									

*Observations continued to day 28, however, no significant reactions were noted beyond day 11.

A blank space indicates no significant reactions.

Riker Experiment No.: 0862AR0E362

APPENDIX I

PROTOCOL

TEST: Acute Oral Toxicity

SPONSOR: 3M Commercial Chemicals Division

CONDUCTED BY: **Safety Evaluation Laboratory, Riker Laboratories, Inc., St. Paul, Minnesota**

TEST ARTICLE: T-3290CoC

CONTROL ARTICLE: NONE

PROPOSED STARTING/COMPLETION DATE OF TEST: 7/82 - 10/82

TEST SYSTEM: ALBINO RAT, SD STRAIN

SOURCE: KING LABS, OREGON, WI

Sex: M, F
Number: 5/5
Weight Range: 200-300 grams

OBJECTIVE: The objective of this test will be to characterize the acute oral toxicity of the test article in albino rats. Rats were selected as a test system for reproducibility of response, historical use, ease in handling and general availability.

METHOD: The animals will be housed in stainless steel suspended wire mesh cages in temperature and humidity controlled rooms during both the quarantine and test periods, with food[a] and water offered *ad libitum*[b]. Each animal will be identified by color coding, according to the laboratory's standard operating procedure, which will correspond to the animal numbers on a card affixed to the outside of the cage. A single dosage of _____* mg/kg will be administered each animal, however, if this dosage level does not adequately characterize the toxicity of the test article, additional animals will be administered the test article at supplemental dosage levels. Any additional dosage levels will be documented and filed with this protocol. The test article will be administered to the animals in the form received from the sponsor, after which the animals will be returned to their cages and observed for any untoward behavioral reactions for the following 14 days. Initial and final body weights will be recorded. A gross necropsy which will include, but not be limited to; heart, lungs, liver, kidneys and general gastrointestinal tract will be conducted on all animals which die during the conduct of the test as well as the animals surviving the test period. Any gross abnormalities which are observed during the conduct of the necropsy will be recorded with specific mention to the organ and/or site observed. All raw data generated by the study director and the final report will be stored in the Riker Laboratories' Archive, St. Paul, Minnesota.

[a] Purina Laboratory Chow, Ralston Purina, St. Louis, Missouri
[b] Purina Chow FOOD WILL BE WITHHELD FOR A [illegible] PERIOD [illegible] TO DOSING
*dose at two levels: 1250 mg/kg & 200 mg/kg (as solids) solution is 50 soli

William T. Lynch 7.29.82
Sponsor Date

D. L. [illegible] 7/30/82
Study Director Date

APPENDIX I (concluded)
Deviations and/or Amendments to Protocol

1. The test article was supplied as a solution with 40% solids not 50%.

D. M. MacRae 7/30/82
Study Director Date

2. _____

Study Director Date

3. _____

Study Director Date

4. _____

Study Director Date

5. _____

Study Director Date

APPENDIX II

Principal Participating Personnel Involved in the Study

Name	Function
H. S. Rhodes	Jr. Laboratory Technician Acute Toxicology
D. M. Markoe, Jr., BS	Toxicologist Study Director
K. L. Ebbens, BS	Supervisor Toxicology Testing
K. D. O'Malley, BS	Senior Toxicologist Acute Toxicology
G. C. Pecore	Supervisor Animal Laboratory

APPENDIX III

Composition Characteristics

This study is not regulated by the Good Laboratory Practice Act of 1978 and therefore information pertaining to composition characteristics is not applicable for inclusion in this study.

APPENDIX IV

Quality Assurance Statement

This study is not officially regulated by the Good Laboratory Practice Regulation of 1978, and therefore a statement signed and prepared by the Compliance Audit department is not applicable.

The standard operating procedures of this laboratory does adhere to the general principles of this regulation. The Compliance Audit department does inspect different significant phases for studies underway in the Acute Toxicology Laboratory on a recurring cycle, and the facilities are examined on a three month schedule. In addition a select number of Research & Development studies are routinely picked at random from the Archives by the Compliance Audit department for review.