

**TDMS No.** 88006-03

**Test Type:** CHRONIC

**Route:** RESPIRATORY EXPOSURE WHOLE BODY

**Species/Strain:** RATS/F 344

**P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

ALPHA-METHYLSTYRENE

**CAS Number:** 98-83-9

**Pathologist:** RENNE, R.

**Date Report Requested:** 02/08/2006

**Time Report Requested:** 15:18:27

**First Dose M/F:** 08/06/01 / 08/06/01

**Lab:** BNW

**C Number:** C88006B  
**Lock Date:** 03/26/2004  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL

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**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.  
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Adrenal Cortex  
Adrenal Medulla  
Brain  
Clitoral/Preputial Gland  
Islets, Pancreatic  
Kidney  
Lung  
Ovary  
Pituitary Gland  
Spleen  
Testes  
Thymus  
Thyroid Gland  
Urinary Bladder

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF ALPHA-METHYLSTYRENE**

**MALE RATS**

**Organ**

Kidney: Renal Tubule

**Morphology**

Adenoma (Step Section)

Adenoma (Step and Original Sections)

Carcinoma or Adenoma (Step Section)

Carcinoma or Adenoma (Step and Original Sections)

Hyperplasia (Step Section)

Hyperplasia (Step and Original Sections)

Hyperplasia and Adenoma (Step Section)

Hyperplasia and Adenoma (Step and Original Sections)

Hyperplasia, Carcinoma or Adenoma

Hyperplasia, Carcinoma or Adenoma (Step Section)

Hyperplasia, Carcinoma or Adenoma (Step and Original Sections)

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Lab: BNW

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

Kidney: Renal Tubule  
Adenoma (Step Section)

TUMOR RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	5/50 (10%)
POLY-3 RATE (b)	1/42.01	2/44.98	1/42	5/40.47
POLY-3 PERCENT (g)	2.4%	4.5%	2.4%	12.4%
TERMINAL (d)	1/27 (4%)	1/32 (3%)	1/23 (4%)	3/22 (14%)
FIRST INCIDENCE	729 (T)	723	729 (T)	653

STATISTICAL TESTS

LIFE TABLE	P=0.018*	P=0.566	P=0.726	P=0.074
POLY 3	P=0.033*	P=0.524	P=0.761	P=0.091
POLY 1.5	P=0.035*	P=0.514	P=0.761	P=0.094
POLY 6	P=0.031*	P=0.536	P=0.759	P=0.089
LOGISTIC REGRESSION	P=0.024*	P=0.566	P=0.726	P=0.086
COCH-ARM / FISHERS	P=0.040*	P=0.500	P=0.753N	P=0.102
ORDER RESTRICTED	P=0.031*	(e)	(e)	(e)

TDMS No. 88006-03  
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 ALPHA-METHYLSTYRENE  
 CAS Number: 98-83-9  
 Pathologist: RENNE, R.

Date Report Requested: 02/08/2006  
 Time Report Requested: 15:18:27  
 First Dose M/F: 08/06/01 / 08/06/01  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

**Kidney: Renal Tubule  
 Adenoma (Step and Original Sections)**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	5/50 (10%)
POLY-3 RATE (b)	1/42.01	2/44.98	2/42.05	5/40.47
POLY-3 PERCENT (g)	2.4%	4.5%	4.8%	12.4%
TERMINAL (d)	1/27 (4%)	1/32 (3%)	1/23 (4%)	3/22 (14%)
FIRST INCIDENCE	729 (T)	723	716	653

**STATISTICAL TESTS**

LIFE TABLE	P=0.024*	P=0.566	P=0.450	P=0.074
POLY 3	P=0.043*	P=0.524	P=0.500	P=0.091
POLY 1.5	P=0.046*	P=0.514	P=0.500	P=0.094
POLY 6	P=0.040*	P=0.536	P=0.498	P=0.089
LOGISTIC REGRESSION	P=0.032*	P=0.566	P=0.469	P=0.086
COCH-ARM / FISHERS	P=0.053	P=0.500	P=0.500	P=0.102
ORDER RESTRICTED	P=0.039*	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

**Kidney: Renal Tubule  
 Carcinoma or Adenoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/42.01	0/44.96	2/42.05	2/40.32
POLY-3 PERCENT (g)	0%	0%	4.8%	5%
TERMINAL (d)	0/27 (0%)	0/32 (0%)	1/23 (4%)	0/22 (0%)
FIRST INCIDENCE	---	---	716	688

**STATISTICAL TESTS**

LIFE TABLE	P=0.100	(e)	P=0.210	P=0.228
POLY 3	P=0.117	(e)	P=0.237	P=0.228
POLY 1.5	P=0.123	(e)	P=0.237	P=0.230
POLY 6	P=0.111	(e)	P=0.235	P=0.225
LOGISTIC REGRESSION	P=0.112	(e)	P=0.221	P=0.227
COCH-ARM / FISHERS	P=0.136	(e)	P=0.247	P=0.247
ORDER RESTRICTED	P=0.108	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

**Kidney: Renal Tubule  
 Carcinoma or Adenoma (Step Section)**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	5/50 (10%)
POLY-3 RATE (b)	1/42.01	2/44.98	1/42	5/40.47
POLY-3 PERCENT (g)	2.4%	4.5%	2.4%	12.4%
TERMINAL (d)	1/27 (4%)	1/32 (3%)	1/23 (4%)	3/22 (14%)
FIRST INCIDENCE	729 (T)	723	729 (T)	653

**STATISTICAL TESTS**

LIFE TABLE	P=0.018*	P=0.566	P=0.726	P=0.074
POLY 3	P=0.033*	P=0.524	P=0.761	P=0.091
POLY 1.5	P=0.035*	P=0.514	P=0.761	P=0.094
POLY 6	P=0.031*	P=0.536	P=0.759	P=0.089
LOGISTIC REGRESSION	P=0.024*	P=0.566	P=0.726	P=0.086
COCH-ARM / FISHERS	P=0.040*	P=0.500	P=0.753N	P=0.102
ORDER RESTRICTED	P=0.031*	(e)	(e)	(e)

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 Species/Strain: RATS/F 344

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

**Kidney: Renal Tubule  
 Carcinoma or Adenoma (Step and Original Sections)**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	3/50 (6%)	7/50 (14%)
POLY-3 RATE (b)	1/42.01	2/44.98	3/42.05	7/40.71
POLY-3 PERCENT (g)	2.4%	4.5%	7.1%	17.2%
TERMINAL (d)	1/27 (4%)	1/32 (3%)	2/23 (9%)	3/22 (14%)
FIRST INCIDENCE	729 (T)	723	716	653

**STATISTICAL TESTS**

LIFE TABLE	P=0.003**	P=0.566	P=0.255	P=0.024*
POLY 3	P=0.006**	P=0.524	P=0.305	P=0.026*
POLY 1.5	P=0.007**	P=0.514	P=0.305	P=0.027*
POLY 6	P=0.006**	P=0.536	P=0.302	P=0.025*
LOGISTIC REGRESSION	P=0.004**	P=0.566	P=0.267	P=0.025*
COCH-ARM / FISHERS	P=0.009**	P=0.500	P=0.309	P=0.030*
ORDER RESTRICTED	P=0.007**	(e)	(e)	(e)



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STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

Kidney: Renal Tubule  
Hyperplasia (Step Section)

TUMOR RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	1/42.01	0/44.96	1/42	4/40.89
POLY-3 PERCENT (g)	2.4%	0%	2.4%	9.8%
TERMINAL (d)	1/27 (4%)	0/32 (0%)	1/23 (4%)	2/22 (9%)
FIRST INCIDENCE	729 (T)	---	729 (T)	579

STATISTICAL TESTS

LIFE TABLE	P=0.013*	P=0.466N	P=0.726	P=0.142
POLY 3	P=0.020*	P=0.486N	P=0.761	P=0.169
POLY 1.5	P=0.021*	P=0.492N	P=0.761	P=0.171
POLY 6	P=0.019*	P=0.480N	P=0.759	P=0.168
LOGISTIC REGRESSION	P=0.021*	(e)	P=0.726	P=0.173
COCH-ARM / FISHERS	P=0.025*	P=0.500N	P=0.753N	P=0.181
ORDER RESTRICTED	P=0.023*	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

**Kidney: Renal Tubule  
 Hyperplasia (Step and Original Sections)**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	5/50 (10%)
POLY-3 RATE (b)	1/42.01	0/44.96	1/42	5/41.06
POLY-3 PERCENT (g)	2.4%	0%	2.4%	12.2%
TERMINAL (d)	1/27 (4%)	0/32 (0%)	1/23 (4%)	2/22 (9%)
FIRST INCIDENCE	729 (T)	---	729 (T)	579

**STATISTICAL TESTS**

LIFE TABLE	P=0.003**	P=0.466N	P=0.726	P=0.083
POLY 3	P=0.005**	P=0.486N	P=0.761	P=0.095
POLY 1.5	P=0.005**	P=0.492N	P=0.761	P=0.096
POLY 6	P=0.005**	P=0.480N	P=0.759	P=0.094
LOGISTIC REGRESSION	P=0.006**	(e)	P=0.726	P=0.098
COCH-ARM / FISHERS	P=0.007**	P=0.500N	P=0.753N	P=0.102
ORDER RESTRICTED	P=0.007**	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

**Kidney: Renal Tubule  
 Hyperplasia and Adenoma (Step Section)**

**TUMOR RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	2/50 (4%)	8/50 (16%)
POLY-3 RATE (b)	2/42.01	2/44.98	2/42	8/41.28
POLY-3 PERCENT (g)	4.8%	4.5%	4.8%	19.4%
TERMINAL (d)	2/27 (7%)	1/32 (3%)	2/23 (9%)	4/22 (18%)
FIRST INCIDENCE	729 (T)	723	729 (T)	579

**STATISTICAL TESTS**

LIFE TABLE	P=0.002**	P=0.626N	P=0.638	P=0.031*
POLY 3	P=0.004**	P=0.669N	P=0.694	P=0.040*
POLY 1.5	P=0.004**	P=0.679N	P=0.694	P=0.041*
POLY 6	P=0.004**	P=0.657N	P=0.692	P=0.040*
LOGISTIC REGRESSION	P=0.003**	P=0.626N	P=0.638	P=0.040*
COCH-ARM / FISHERS	P=0.006**	P=0.691N	P=0.691N	P=0.046*
ORDER RESTRICTED	P=0.009**	(e)	(e)	(e)

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 Species/Strain: RATS/F 344

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

**Kidney: Renal Tubule  
 Hyperplasia and Adenoma (Step and Original Sections)**

**TUMOR RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	3/50 (6%)	9/50 (18%)
POLY-3 RATE (b)	2/42.01	2/44.98	3/42.05	9/41.45
POLY-3 PERCENT (g)	4.8%	4.5%	7.1%	21.7%
TERMINAL (d)	2/27 (7%)	1/32 (3%)	2/23 (9%)	4/22 (18%)
FIRST INCIDENCE	729 (T)	723	716	579

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.626N	P=0.431	P=0.018*
POLY 3	P=0.002**	P=0.669N	P=0.500	P=0.022*
POLY 1.5	P=0.002**	P=0.679N	P=0.500	P=0.023*
POLY 6	P=0.002**	P=0.657N	P=0.497	P=0.022*
LOGISTIC REGRESSION	P<0.001**	P=0.626N	P=0.450	P=0.023*
COCH-ARM / FISHERS	P=0.003**	P=0.691N	P=0.500	P=0.026*
ORDER RESTRICTED	P=0.004**	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

**Kidney: Renal Tubule  
 Hyperplasia, Carcinoma or Adenoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	0/42.01	0/44.96	2/42.05	3/40.5
POLY-3 PERCENT (g)	0%	0%	4.8%	7.4%
TERMINAL (d)	0/27 (0%)	0/32 (0%)	1/23 (4%)	0/22 (0%)
FIRST INCIDENCE	---	---	716	684

**STATISTICAL TESTS**

LIFE TABLE	P=0.027*	(e)	P=0.210	P=0.118
POLY 3	P=0.033*	(e)	P=0.237	P=0.112
POLY 1.5	P=0.035*	(e)	P=0.237	P=0.114
POLY 6	P=0.031*	(e)	P=0.235	P=0.110
LOGISTIC REGRESSION	P=0.032*	(e)	P=0.221	P=0.113
COCH-ARM / FISHERS	P=0.041*	(e)	P=0.247	P=0.121
ORDER RESTRICTED	P=0.033*	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

**Kidney: Renal Tubule  
 Hyperplasia, Carcinoma or Adenoma (Step Section)**

**TUMOR RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	2/50 (4%)	8/50 (16%)
POLY-3 RATE (b)	2/42.01	2/44.98	2/42	8/41.28
POLY-3 PERCENT (g)	4.8%	4.5%	4.8%	19.4%
TERMINAL (d)	2/27 (7%)	1/32 (3%)	2/23 (9%)	4/22 (18%)
FIRST INCIDENCE	729 (T)	723	729 (T)	579

**STATISTICAL TESTS**

LIFE TABLE	P=0.002**	P=0.626N	P=0.638	P=0.031*
POLY 3	P=0.004**	P=0.669N	P=0.694	P=0.040*
POLY 1.5	P=0.004**	P=0.679N	P=0.694	P=0.041*
POLY 6	P=0.004**	P=0.657N	P=0.692	P=0.040*
LOGISTIC REGRESSION	P=0.003**	P=0.626N	P=0.638	P=0.040*
COCH-ARM / FISHERS	P=0.006**	P=0.691N	P=0.691N	P=0.046*
ORDER RESTRICTED	P=0.009**	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	CONTROL	100 PPM	300 PPM	1000 PPM

**Kidney: Renal Tubule  
 Hyperplasia, Carcinoma or Adenoma (Step and Original Sections)**

**TUMOR RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	4/50 (8%)	11/50 (22%)
POLY-3 RATE (b)	2/42.01	2/44.98	4/42.05	11/41.69
POLY-3 PERCENT (g)	4.8%	4.5%	9.5%	26.4%
TERMINAL (d)	2/27 (7%)	1/32 (3%)	3/23 (13%)	4/22 (18%)
FIRST INCIDENCE	729 (T)	723	716	579

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.626N	P=0.268	P=0.006**
POLY 3	P<0.001**	P=0.669N	P=0.337	P=0.006**
POLY 1.5	P<0.001**	P=0.679N	P=0.337	P=0.006**
POLY 6	P<0.001**	P=0.657N	P=0.332	P=0.006**
LOGISTIC REGRESSION	P<0.001**	P=0.626N	P=0.281	P=0.007**
COCH-ARM / FISHERS	P<0.001**	P=0.691N	P=0.339	P=0.007**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)

TDMS No. 88006-03

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/F 344

**P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

ALPHA-METHYLSTYRENE

CAS Number: 98-83-9

Pathologist: RENNE, R.

Date Report Requested: 02/08/2006

Time Report Requested: 15:18:27

First Dose M/F: 08/06/01 / 08/06/01

Lab: BNW

**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
  - (e) Value of Statistic cannot be computed.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.  
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

\*\*\* END OF REPORT \*\*\*