

TDMS No. 99023 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

beta-Myrcene
CAS Number: 123-35-3

Date Report Requested: 04/29/2008
Time Report Requested: 16:23:25
First Dose M/F: 03/25/02 / 03/26/02
Lab: BAT

STEP SECTION REPORT

C Number: C99023
Lock Date: 12/22/2004
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include 001 0 G/KG Include 002 0 G/KG Include 003 0.25 G/KG
 Include 004 0.25 G/KG Include 005 0.5 G/KG Include 006 0.5 G/KG
 Include 008 1.0 G/KG
Gender: Both
TDMSE Version: 2.0.0c

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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.**

Kidney

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF beta-Myrcene

MALE RATS

Organ

Kidney: Renal Tubule

Morphology

Adenoma
Adenoma (Step Section)
Adenoma (Step or Original Sections)
Carcinoma
Carcinoma (Step Section)
Carcinoma (Step or Original Sections)
Adenoma or Carcinoma
Adenoma or Carcinoma (Step Section)
Adenoma or Carcinoma (Step or Original Sections)
Adenoma or Hyperplasia
Adenoma or Hyperplasia (Step Section)
Adenoma or Hyperplasia (Step or Original Sections)
Adenoma Carcinoma or Hyperplasia
Adenoma Carcinoma or Hyperplasia (Step Section)
Adenoma Carcinoma or Hyperplasia (Step or Original Sections)

FEMALE RATS

Organ

Kidney: Renal Tubule

Morphology

Adenoma (Step or Original Sections)
Hyperplasia (Step Section)
Hyperplasia (Step or Original Sections)
Adenoma or Carcinoma (Step or Original Sections)
Adenoma or Hyperplasia
Adenoma or Hyperplasia (Step Section)
Adenoma or Hyperplasia (Step or Original Sections)
Adenoma Carcinoma or Hyperplasia
Adenoma Carcinoma or Hyperplasia (Step Section)
Adenoma Carcinoma or Hyperplasia (Step or Original Sections)

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

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

**Kidney: Renal Tubule
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	4/50 (8%)	8/50 (16%)
POLY-3 RATE (b)	0/42.71	4/45.25	8/42.91
POLY-3 PERCENT (g)	0%	8.8%	18.7%
TERMINAL (d)	0/29 (0%)	3/36 (8%)	5/28 (18%)
FIRST INCIDENCE	---	717	551

STATISTICAL TESTS

POLY 3	P=0.002**	P=0.068	P=0.003**
POLY 1.5	P=0.002**	P=0.064	P=0.003**
POLY 6	P=0.002**	P=0.073	P=0.004**
COCH-ARM / FISHERS	P=0.003**	P=0.059	P=0.003**
MAX-ISO-POLY-3	P<0.001**	P=0.025*	P<0.001**

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

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

Kidney: Renal Tubule
Adenoma (Step Section)

TUMOR RATES

OVERALL (a)	0/50 (0%)	8/50 (16%)	7/50 (14%)
POLY-3 RATE (b)	0/42.71	8/45.2	7/42.77
POLY-3 PERCENT (g)	0%	17.7%	16.4%
TERMINAL (d)	0/29 (0%)	8/36 (22%)	4/28 (14%)
FIRST INCIDENCE	---	729 (T)	551

STATISTICAL TESTS

POLY 3	P=0.013*	P=0.005**	P=0.007**
POLY 1.5	P=0.012*	P=0.004**	P=0.007**
POLY 6	P=0.014*	P=0.005**	P=0.007**
COCH-ARM / FISHERS	P=0.015*	P=0.003**	P=0.006**
MAX-ISO-POLY-3	P=0.008**	P=0.002**	P=0.002**

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

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	12/50 (24%)	13/50 (26%)
POLY-3 RATE (b)	0/42.71	12/45.25	13/43.01
POLY-3 PERCENT (g)	0%	26.5%	30.2%
TERMINAL (d)	0/29 (0%)	11/36 (31%)	9/28 (32%)
FIRST INCIDENCE	---	717	551

STATISTICAL TESTS

POLY 3	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**

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

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

Kidney: Renal Tubule
Carcinoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/42.71	3/45.48	1/41.86
POLY-3 PERCENT (g)	0%	6.6%	2.4%
TERMINAL (d)	0/29 (0%)	2/36 (6%)	1/28 (4%)
FIRST INCIDENCE	---	652	729 (T)

STATISTICAL TESTS

POLY 3	P=0.369	P=0.130	P=0.496
POLY 1.5	P=0.366	P=0.125	P=0.495
POLY 6	P=0.368	P=0.138	P=0.496
COCH-ARM / FISHERS	P=0.378	P=0.121	P=0.500
MAX-ISO-POLY-3	P=0.160	P=0.048*	P=0.158

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

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/42.71	3/45.48	0/41.86
POLY-3 PERCENT (g)	0%	6.6%	0%
TERMINAL (d)	0/29 (0%)	2/36 (6%)	0/28 (0%)
FIRST INCIDENCE	---	652	---

STATISTICAL TESTS

POLY 3	P=0.631	P=0.130	(e)
POLY 1.5	P=0.629	P=0.125	(e)
POLY 6	P=0.631	P=0.138	(e)
COCH-ARM / FISHERS	P=0.640	P=0.121	(e)
MAX-ISO-POLY-3	P=0.208	P=0.048*	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/42.71	3/45.48	1/41.86
POLY-3 PERCENT (g)	0%	6.6%	2.4%
TERMINAL (d)	0/29 (0%)	2/36 (6%)	1/28 (4%)
FIRST INCIDENCE	---	652	729 (T)

STATISTICAL TESTS

POLY 3	P=0.369	P=0.130	P=0.496
POLY 1.5	P=0.366	P=0.125	P=0.495
POLY 6	P=0.368	P=0.138	P=0.496
COCH-ARM / FISHERS	P=0.378	P=0.121	P=0.500
MAX-ISO-POLY-3	P=0.160	P=0.048*	P=0.158

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

**Kidney: Renal Tubule
 Hyperplasia**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.71	0/45.2	2/41.86
POLY-3 PERCENT (g)	0%	0%	4.8%
TERMINAL (d)	0/29 (0%)	0/36 (0%)	2/28 (7%)
FIRST INCIDENCE	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.094	(e)	P=0.232
POLY 1.5	P=0.094	(e)	P=0.231
POLY 6	P=0.094	(e)	P=0.232
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.052	(e)	P=0.076

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

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

TUMOR RATES

OVERALL (a)	1/50 (2%)	5/50 (10%)	1/50 (2%)
POLY-3 RATE (b)	1/42.71	5/45.62	1/41.86
POLY-3 PERCENT (g)	2.3%	11%	2.4%
TERMINAL (d)	1/29 (3%)	3/36 (8%)	1/28 (4%)
FIRST INCIDENCE	729 (T)	611	729 (T)

STATISTICAL TESTS

POLY 3	P=0.582	P=0.117	P=0.756
POLY 1.5	P=0.578	P=0.110	P=0.755
POLY 6	P=0.581	P=0.128	P=0.756
COCH-ARM / FISHERS	P=0.594	P=0.102	P=0.753N
MAX-ISO-POLY-3	P=0.254	P=0.059	P=0.493

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

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

Kidney: Renal Tubule
Hyperplasia (Step or Original Sections)

TUMOR RATES

OVERALL (a)	1/50 (2%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	1/42.71	5/45.62	3/41.86
POLY-3 PERCENT (g)	2.3%	11%	7.2%
TERMINAL (d)	1/29 (3%)	3/36 (8%)	3/28 (11%)
FIRST INCIDENCE	729 (T)	611	729 (T)

STATISTICAL TESTS

POLY 3	P=0.253	P=0.117	P=0.298
POLY 1.5	P=0.250	P=0.110	P=0.296
POLY 6	P=0.251	P=0.128	P=0.297
COCH-ARM / FISHERS	P=0.264	P=0.102	P=0.309
MAX-ISO-POLY-3	P=0.156	P=0.059	P=0.150

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

**Kidney: Renal Tubule
 Adenoma or Carcinoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	7/50 (14%)	9/50 (18%)
POLY-3 RATE (b)	0/42.71	7/45.53	9/42.91
POLY-3 PERCENT (g)	0%	15.4%	21%
TERMINAL (d)	0/29 (0%)	5/36 (14%)	6/28 (21%)
FIRST INCIDENCE	---	652	551

STATISTICAL TESTS

POLY 3	P=0.002**	P=0.010**	P=0.002**
POLY 1.5	P=0.002**	P=0.009**	P=0.002**
POLY 6	P=0.002**	P=0.011*	P=0.002**
COCH-ARM / FISHERS	P=0.003**	P=0.006**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.004**	P<0.001**

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	10/50 (20%)	7/50 (14%)
POLY-3 RATE (b)	0/42.71	10/45.48	7/42.77
POLY-3 PERCENT (g)	0%	22%	16.4%
TERMINAL (d)	0/29 (0%)	9/36 (25%)	4/28 (14%)
FIRST INCIDENCE	---	652	551

STATISTICAL TESTS

POLY 3	P=0.017*	P<0.001**	P=0.007**
POLY 1.5	P=0.015*	P<0.001**	P=0.007**
POLY 6	P=0.018*	P<0.001**	P=0.007**
COCH-ARM / FISHERS	P=0.020*	P<0.001**	P=0.006**
MAX-ISO-POLY-3	P=0.004**	P<0.001**	P=0.002**

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	14/50 (28%)	13/50 (26%)
POLY-3 RATE (b)	0/42.71	14/45.53	13/43.01
POLY-3 PERCENT (g)	0%	30.8%	30.2%
TERMINAL (d)	0/29 (0%)	12/36 (33%)	9/28 (32%)
FIRST INCIDENCE	---	652	551

STATISTICAL TESTS

POLY 3	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

**Kidney: Renal Tubule
 Adenoma or Hyperplasia**

TUMOR RATES

OVERALL (a)	0/50 (0%)	4/50 (8%)	10/50 (20%)
POLY-3 RATE (b)	0/42.71	4/45.25	10/42.91
POLY-3 PERCENT (g)	0%	8.8%	23.3%
TERMINAL (d)	0/29 (0%)	3/36 (8%)	7/28 (25%)
FIRST INCIDENCE	---	717	551

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.068	P<0.001**
POLY 1.5	P<0.001**	P=0.064	P<0.001**
POLY 6	P<0.001**	P=0.073	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.059	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.025*	P<0.001**

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TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

Kidney: Renal Tubule
Adenoma or Hyperplasia (Step Section)

TUMOR RATES

OVERALL (a)	1/50 (2%)	13/50 (26%)	8/50 (16%)
POLY-3 RATE (b)	1/42.71	13/45.62	8/42.77
POLY-3 PERCENT (g)	2.3%	28.5%	18.7%
TERMINAL (d)	1/29 (3%)	11/36 (31%)	5/28 (18%)
FIRST INCIDENCE	729 (T)	611	551

STATISTICAL TESTS

POLY 3	P=0.027*	P<0.001**	P=0.015*
POLY 1.5	P=0.025*	P<0.001**	P=0.014*
POLY 6	P=0.029*	P<0.001**	P=0.016*
COCH-ARM / FISHERS	P=0.033*	P<0.001**	P=0.015*
MAX-ISO-POLY-3	P=0.004**	P<0.001**	P=0.006**

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

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

TUMOR RATES

OVERALL (a)	1/50 (2%)	17/50 (34%)	16/50 (32%)
POLY-3 RATE (b)	1/42.71	17/45.67	16/43.01
POLY-3 PERCENT (g)	2.3%	37.2%	37.2%
TERMINAL (d)	1/29 (3%)	14/36 (39%)	12/28 (43%)
FIRST INCIDENCE	729 (T)	611	551

STATISTICAL TESTS

POLY 3	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	7/50 (14%)	11/50 (22%)
POLY-3 RATE (b)	0/42.71	7/45.53	11/42.91
POLY-3 PERCENT (g)	0%	15.4%	25.6%
TERMINAL (d)	0/29 (0%)	5/36 (14%)	8/28 (29%)
FIRST INCIDENCE	---	652	551

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.010**	P<0.001**
POLY 1.5	P<0.001**	P=0.009**	P<0.001**
POLY 6	P<0.001**	P=0.011*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.006**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.004**	P<0.001**

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

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

TUMOR RATES

OVERALL (a)	1/50 (2%)	15/50 (30%)	8/50 (16%)
POLY-3 RATE (b)	1/42.71	15/45.91	8/42.77
POLY-3 PERCENT (g)	2.3%	32.7%	18.7%
TERMINAL (d)	1/29 (3%)	12/36 (33%)	5/28 (18%)
FIRST INCIDENCE	729 (T)	611	551

STATISTICAL TESTS

POLY 3	P=0.030*	P<0.001**	P=0.015*
POLY 1.5	P=0.028*	P<0.001**	P=0.014*
POLY 6	P=0.033*	P<0.001**	P=0.016*
COCH-ARM / FISHERS	P=0.038*	P<0.001**	P=0.015*
MAX-ISO-POLY-3	P=0.002**	P<0.001**	P=0.006**

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Males		
	0 G/KG	0.25 G/KG	0.5 G/KG

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

TUMOR RATES

OVERALL (a)	1/50 (2%)	19/50 (38%)	16/50 (32%)
POLY-3 RATE (b)	1/42.71	19/45.95	16/43.01
POLY-3 PERCENT (g)	2.3%	41.4%	37.2%
TERMINAL (d)	1/29 (3%)	15/36 (42%)	12/28 (43%)
FIRST INCIDENCE	729 (T)	611	551

STATISTICAL TESTS

POLY 3	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

**Kidney: Renal Tubule
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/41.3	1/41.64	0/39.36	2/41.89
POLY-3 PERCENT (g)	0%	2.4%	0%	4.8%
TERMINAL (d)	0/31 (0%)	1/33 (3%)	0/28 (0%)	2/33 (6%)
FIRST INCIDENCE	---	730 (T)	---	730 (T)

STATISTICAL TESTS

POLY 3	P=0.140	P=0.502	(e)	P=0.240
POLY 1.5	P=0.137	P=0.500	(e)	P=0.234
POLY 6	P=0.144	P=0.504	(e)	P=0.247
COCH-ARM / FISHERS	P=0.140	P=0.500	(e)	P=0.247
MAX-ISO-POLY-3	P=0.081	P=0.160	(e)	P=0.079

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/41.3	1/41.8	1/39.48	2/41.89
POLY-3 PERCENT (g)	0%	2.4%	2.5%	4.8%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	0/28 (0%)	2/33 (6%)
FIRST INCIDENCE	---	689	701	730 (T)

STATISTICAL TESTS

POLY 3	P=0.156	P=0.502	P=0.491	P=0.240
POLY 1.5	P=0.150	P=0.500	P=0.494	P=0.234
POLY 6	P=0.162	P=0.506	P=0.488	P=0.247
COCH-ARM / FISHERS	P=0.153	P=0.500	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.126	P=0.161	P=0.158	P=0.079

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/41.3	2/41.8	1/39.48	3/41.89
POLY-3 PERCENT (g)	0%	4.8%	2.5%	7.2%
TERMINAL (d)	0/31 (0%)	1/33 (3%)	0/28 (0%)	3/33 (9%)
FIRST INCIDENCE	---	689	701	730 (T)

STATISTICAL TESTS

POLY 3	P=0.105	P=0.239	P=0.491	P=0.121
POLY 1.5	P=0.100	P=0.237	P=0.494	P=0.116
POLY 6	P=0.110	P=0.243	P=0.488	P=0.126
COCH-ARM / FISHERS	P=0.104	P=0.247	P=0.500	P=0.121
MAX-ISO-POLY-3	P=0.063	P=0.078	P=0.158	P=0.040*

TDMS No. 99023 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
beta-Myrcene
CAS Number: 123-35-3

Date Report Requested: 04/29/2008
Time Report Requested: 16:23:25
First Dose M/F: 03/25/02 / 03/26/02
Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

Kidney: Renal Tubule
Carcinoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/41.3	0/41.64	0/39.36	0/41.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	0/28 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/41.3	0/41.64	0/39.36	0/41.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	0/28 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/41.3	0/41.64	0/39.36	0/41.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	0/28 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

**Kidney: Renal Tubule
 Hyperplasia**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/41.3	0/41.64	0/39.36	1/41.89
POLY-3 PERCENT (g)	0%	0%	0%	2.4%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	0/28 (0%)	1/33 (3%)
FIRST INCIDENCE	---	---	---	730 (T)

STATISTICAL TESTS

POLY 3	P=0.200	(e)	(e)	P=0.503
POLY 1.5	P=0.197	(e)	(e)	P=0.498
POLY 6	P=0.204	(e)	(e)	P=0.509
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.128	(e)	(e)	P=0.162

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

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

TUMOR RATES

OVERALL (a)	1/50 (2%)	5/50 (10%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/41.3	5/42.36	1/39.36	1/41.89
POLY-3 PERCENT (g)	2.4%	11.8%	2.5%	2.4%
TERMINAL (d)	1/31 (3%)	4/33 (12%)	1/28 (4%)	1/33 (3%)
FIRST INCIDENCE	730 (T)	476	730 (T)	730 (T)

STATISTICAL TESTS

POLY 3	P=0.307N	P=0.106	P=0.750	P=0.758N
POLY 1.5	P=0.318N	P=0.103	P=0.754	P=0.758
POLY 6	P=0.295N	P=0.110	P=0.747	P=0.751N
COCH-ARM / FISHERS	P=0.313N	P=0.102	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.248N	P=0.049*	P=0.486	P=0.495N

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

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

TUMOR RATES

OVERALL (a)	1/50 (2%)	5/50 (10%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/41.3	5/42.36	1/39.36	2/41.89
POLY-3 PERCENT (g)	2.4%	11.8%	2.5%	4.8%
TERMINAL (d)	1/31 (3%)	4/33 (12%)	1/28 (4%)	2/33 (6%)
FIRST INCIDENCE	730 (T)	476	730 (T)	730 (T)

STATISTICAL TESTS

POLY 3	P=0.520N	P=0.106	P=0.750	P=0.505
POLY 1.5	P=0.531N	P=0.103	P=0.754	P=0.496
POLY 6	P=0.507N	P=0.110	P=0.747	P=0.515
COCH-ARM / FISHERS	P=0.523N	P=0.102	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.336	P=0.049*	P=0.486	P=0.286

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

**Kidney: Renal Tubule
 Adenoma or Carcinoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/41.3	1/41.64	0/39.36	2/41.89
POLY-3 PERCENT (g)	0%	2.4%	0%	4.8%
TERMINAL (d)	0/31 (0%)	1/33 (3%)	0/28 (0%)	2/33 (6%)
FIRST INCIDENCE	---	730 (T)	---	730 (T)

STATISTICAL TESTS

POLY 3	P=0.140	P=0.502	(e)	P=0.240
POLY 1.5	P=0.137	P=0.500	(e)	P=0.234
POLY 6	P=0.144	P=0.504	(e)	P=0.247
COCH-ARM / FISHERS	P=0.140	P=0.500	(e)	P=0.247
MAX-ISO-POLY-3	P=0.081	P=0.160	(e)	P=0.079

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/41.3	1/41.8	1/39.48	2/41.89
POLY-3 PERCENT (g)	0%	2.4%	2.5%	4.8%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	0/28 (0%)	2/33 (6%)
FIRST INCIDENCE	---	689	701	730 (T)

STATISTICAL TESTS

POLY 3	P=0.156	P=0.502	P=0.491	P=0.240
POLY 1.5	P=0.150	P=0.500	P=0.494	P=0.234
POLY 6	P=0.162	P=0.506	P=0.488	P=0.247
COCH-ARM / FISHERS	P=0.153	P=0.500	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.126	P=0.161	P=0.158	P=0.079

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

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

TUMOR RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/41.3	2/41.8	1/39.48	3/41.89
POLY-3 PERCENT (g)	0%	4.8%	2.5%	7.2%
TERMINAL (d)	0/31 (0%)	1/33 (3%)	0/28 (0%)	3/33 (9%)
FIRST INCIDENCE	---	689	701	730 (T)

STATISTICAL TESTS

POLY 3	P=0.105	P=0.239	P=0.491	P=0.121
POLY 1.5	P=0.100	P=0.237	P=0.494	P=0.116
POLY 6	P=0.110	P=0.243	P=0.488	P=0.126
COCH-ARM / FISHERS	P=0.104	P=0.247	P=0.500	P=0.121
MAX-ISO-POLY-3	P=0.063	P=0.078	P=0.158	P=0.040*

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

**Kidney: Renal Tubule
 Adenoma or Hyperplasia**

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/41.3	1/41.64	0/39.36	3/41.89
POLY-3 PERCENT (g)	0%	2.4%	0%	7.2%
TERMINAL (d)	0/31 (0%)	1/33 (3%)	0/28 (0%)	3/33 (9%)
FIRST INCIDENCE	---	730 (T)	---	730 (T)

STATISTICAL TESTS

POLY 3	P=0.043*	P=0.502	(e)	P=0.121
POLY 1.5	P=0.042*	P=0.500	(e)	P=0.116
POLY 6	P=0.044*	P=0.504	(e)	P=0.126
COCH-ARM / FISHERS	P=0.044*	P=0.500	(e)	P=0.121
MAX-ISO-POLY-3	P=0.025*	P=0.160	(e)	P=0.040*

TDMS No. 99023 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 beta-Myrcene
 CAS Number: 123-35-3

Date Report Requested: 04/29/2008
 Time Report Requested: 16:23:25
 First Dose M/F: 03/25/02 / 03/26/02
 Lab: BAT

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

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

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

TUMOR RATES

OVERALL (a)	1/50 (2%)	6/50 (12%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	1/41.3	6/42.52	2/39.48	3/41.89
POLY-3 PERCENT (g)	2.4%	14.1%	5.1%	7.2%
TERMINAL (d)	1/31 (3%)	4/33 (12%)	1/28 (4%)	3/33 (9%)
FIRST INCIDENCE	730 (T)	476	701	730 (T)

STATISTICAL TESTS

POLY 3	P=0.506	P=0.060	P=0.484	P=0.310
POLY 1.5	P=0.490	P=0.057	P=0.489	P=0.301
POLY 6	P=0.525	P=0.063	P=0.480	P=0.320
COCH-ARM / FISHERS	P=0.500	P=0.056	P=0.500	P=0.309
MAX-ISO-POLY-3	P=0.205	P=0.027*	P=0.271	P=0.159

TDMS No. 99023 - 03
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FIRST INCIDENCE	730 (T)	476	701	730 (T)

STATISTICAL TESTS

POLY 3	P=0.199	P=0.060	P=0.484	P=0.104
POLY 1.5	P=0.190	P=0.057	P=0.489	P=0.098
POLY 6	P=0.211	P=0.063	P=0.480	P=0.110
COCH-ARM / FISHERS	P=0.200	P=0.056	P=0.500	P=0.102
MAX-ISO-POLY-3	P=0.092	P=0.027*	P=0.271	P=0.046*

TDMS No. 99023 - 03
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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.
 - (e) Value of Statistic cannot be computed.
 - (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.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (h) Value of Historical Controls statistic is only calculated when Poly-3 trend is positive and when there is more than one tumor in the treatment groups.
 - (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
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***