

TDMS No. 20304 - 01
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/SD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

TEF evaluation (PCB 118)
CAS Number: 31508-00-6

Date Report Requested: 06/26/2008
Time Report Requested: 12:21:48
First Dose M/F: NA / 03/26/04
Lab: BAT

F1_R8_C_S

C Number: C20304
Lock Date: 10/12/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: 25022 ACCK 25021 TSAC 25020 NATD
25019 MSAC 25018 DACC
Removal Date Range: ALL
Treatment Groups: Include 001 0 UG/KG Include 009 4600 UG/KG STOP
Study Gender: Female
TDMSE Version: 2.0.0

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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
Kidney
Liver
Ovary
Pituitary Gland
Thyroid Gland

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF TEF evaluation (PCB 118)

FEMALE RATS

Organ

Liver
Mammary Gland

Thyroid Gland: C-Cell
Uterus
All Organs

Morphology

Cholangiocarcinoma
Fibroadenoma
Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Carcinoma or Adenoma
Carcinoma
Benign Tumors
Malignant Tumors

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

Females

DOSE	0 UG/KG	4600 UG/KG STOP
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**Adrenal Medulla
Pheochromocytoma Benign**

TUMOR RATES

OVERALL (a)	3/52 (6%)	2/49 (4%)
POLY-3 RATE (b)	3/36.16	2/39.73
POLY-3 PERCENT (g)	8.3%	5%
TERMINAL (d)	1/21 (5%)	2/25 (8%)
FIRST INCIDENCE	512	733 (T)
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.457N
POLY 1.5	P=0.483N
POLY 6	P=0.433N
COCH-ARM / FISHERS	P=0.528N
MAX-ISO-POLY-3	P=0.295N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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DOSE	0 UG/KG	4600 UG/KG STOP
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Liver
Cholangiocarcinoma

TUMOR RATES

OVERALL (a)	0/52 (0%)	29/49 (59%)
POLY-3 RATE (b)	0/35.12	29/42.62
POLY-3 PERCENT (g)	0%	68.1%
TERMINAL (d)	0/21 (0%)	17/25 (68%)
FIRST INCIDENCE	---	567
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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**Mammary Gland
 Carcinoma**

TUMOR RATES	#	#
OVERALL (a)	2/52 (4%)	2/50 (4%)
POLY-3 RATE (b)	2/35.79	2/40.85
POLY-3 PERCENT (g)	5.6%	4.9%
TERMINAL (d)	1/21 (5%)	0/25 (0%)
FIRST INCIDENCE	503	545
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.646N
POLY 1.5	P=0.672N
POLY 6	P=0.616N
COCH-ARM / FISHERS	P=0.676
MAX-ISO-POLY-3	P=0.448N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE 0 UG/KG 4600 UG/KG
STOP

Mammary Gland
Fibroadenoma

TUMOR RATES	#	#
OVERALL (a)	25/52 (48%)	17/50 (34%)
POLY-3 RATE (b)	25/43.94	17/43.27
POLY-3 PERCENT (g)	56.9%	39.3%
TERMINAL (d)	8/21 (38%)	9/25 (36%)
FIRST INCIDENCE	320	302
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.069N
POLY 1.5	P=0.079N
POLY 6	P=0.068N
COCH-ARM / FISHERS	P=0.107N
MAX-ISO-POLY-3	P=0.045N*
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE 0 UG/KG 4600 UG/KG
STOP

Pituitary Gland: Pars Distalis or Unspecified Site
Adenoma

TUMOR RATES

OVERALL (a)	17/52 (33%)	12/50 (24%)
POLY-3 RATE (b)	17/37.11	12/40.05
POLY-3 PERCENT (g)	45.8%	30%
TERMINAL (d)	11/21 (52%)	10/25 (40%)
FIRST INCIDENCE	440	672
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.107N
POLY 1.5	P=0.149N
POLY 6	P=0.076N
COCH-ARM / FISHERS	P=0.226N
MAX-ISO-POLY-3	P=0.077N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE 0 UG/KG 4600 UG/KG
STOP

Pituitary Gland: Pars Distalis or Unspecified Site
Carcinoma

TUMOR RATES

OVERALL (a)	2/52 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/35.78	1/39.74
POLY-3 PERCENT (g)	5.6%	2.5%
TERMINAL (d)	1/21 (5%)	1/25 (4%)
FIRST INCIDENCE	512	733 (T)
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.463N
POLY 1.5	P=0.484N
POLY 6	P=0.442N
COCH-ARM / FISHERS	P=0.515N
MAX-ISO-POLY-3	P=0.261N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE 0 UG/KG 4600 UG/KG
STOP

Pituitary Gland: Pars Distalis or Unspecified Site
Carcinoma or Adenoma

TUMOR RATES

OVERALL (a)	19/52 (37%)	13/50 (26%)
POLY-3 RATE (b)	19/37.77	13/40.05
POLY-3 PERCENT (g)	50.3%	32.5%
TERMINAL (d)	12/21 (57%)	11/25 (44%)
FIRST INCIDENCE	440	672
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.077N
POLY 1.5	P=0.110N
POLY 6	P=0.053N
COCH-ARM / FISHERS	P=0.175N
MAX-ISO-POLY-3	P=0.054N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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DOSE 0 UG/KG 4600 UG/KG
STOP

Skin
Fibroma

TUMOR RATES	#	#
OVERALL (a)	2/52 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/35.97	1/40.14
POLY-3 PERCENT (g)	5.6%	2.5%
TERMINAL (d)	0/21 (0%)	0/25 (0%)
FIRST INCIDENCE	561	617
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.462N
POLY 1.5	P=0.483N
POLY 6	P=0.441N
COCH-ARM / FISHERS	P=0.515N
MAX-ISO-POLY-3	P=0.260N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE	0 UG/KG	4600 UG/KG STOP
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Stomach, Forestomach
Squamous Cell Carcinoma or Papilloma Squamous

TUMOR RATES	#	#
OVERALL (a)	0/52 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/35.12	2/39.74
POLY-3 PERCENT (g)	0%	5%
TERMINAL (d)	0/21 (0%)	2/25 (8%)
FIRST INCIDENCE	---	733 (T)
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.265
POLY 1.5	P=0.250
POLY 6	P=0.283
COCH-ARM / FISHERS	P=0.238
MAX-ISO-POLY-3	P=0.104
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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Females

DOSE 0 UG/KG 4600 UG/KG
STOP

Thyroid Gland: C-Cell
Adenoma

TUMOR RATES

OVERALL (a)	9/51 (18%)	5/50 (10%)
POLY-3 RATE (b)	9/37.33	5/40.22
POLY-3 PERCENT (g)	24.1%	12.4%
TERMINAL (d)	5/21 (24%)	4/25 (16%)
FIRST INCIDENCE	503	589
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.147N
POLY 1.5	P=0.170N
POLY 6	P=0.125N
COCH-ARM / FISHERS	P=0.206N
MAX-ISO-POLY-3	P=0.097N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE 0 UG/KG 4600 UG/KG
STOP

Thyroid Gland: C-Cell
Carcinoma

TUMOR RATES

OVERALL (a)	2/51 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/35.05	0/39.74
POLY-3 PERCENT (g)	5.7%	0%
TERMINAL (d)	2/21 (10%)	0/25 (0%)
FIRST INCIDENCE	733 (T)	---
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.210N
POLY 1.5	P=0.223N
POLY 6	P=0.195N
COCH-ARM / FISHERS	P=0.252N
MAX-ISO-POLY-3	P=0.075N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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TERMINAL SACRIFICE AT 105 WEEKS

Females

DOSE 0 UG/KG 4600 UG/KG
STOP

Thyroid Gland: C-Cell
Carcinoma or Adenoma

TUMOR RATES

OVERALL (a)	11/51 (22%)	5/50 (10%)
POLY-3 RATE (b)	11/37.33	5/40.22
POLY-3 PERCENT (g)	29.5%	12.4%
TERMINAL (d)	7/21 (33%)	4/25 (16%)
FIRST INCIDENCE	503	589
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.054N
POLY 1.5	P=0.069N
POLY 6	P=0.042N*
COCH-ARM / FISHERS	P=0.093N
MAX-ISO-POLY-3	P=0.034N*
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE **0 UG/KG** **4600 UG/KG
 STOP**

**Uterus
 Carcinoma**

TUMOR RATES	#	#
OVERALL (a)	2/52 (4%)	11/50 (22%)
POLY-3 RATE (b)	2/35.12	11/40.86
POLY-3 PERCENT (g)	5.7%	26.9%
TERMINAL (d)	2/21 (10%)	6/25 (24%)
FIRST INCIDENCE	733 (T)	642
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.014*
POLY 1.5	P=0.009**
POLY 6	P=0.022*
COCH-ARM / FISHERS	P=0.006**
MAX-ISO-POLY-3	P=0.010**
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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Females

DOSE	0 UG/KG	4600 UG/KG STOP
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**Uterus
 Polyp Stromal**

TUMOR RATES	#	#
OVERALL (a)	3/52 (6%)	4/50 (8%)
POLY-3 RATE (b)	3/35.9	4/39.74
POLY-3 PERCENT (g)	8.4%	10.1%
TERMINAL (d)	1/21 (5%)	4/25 (16%)
FIRST INCIDENCE	617	733 (T)
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.556
POLY 1.5	P=0.525
POLY 6	P=0.585
COCH-ARM / FISHERS	P=0.478
MAX-ISO-POLY-3	P=0.403
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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Females

DOSE	0 UG/KG	4600 UG/KG STOP
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All Organs
Benign Tumors

TUMOR RATES	#	#
OVERALL (a)	43/52 (83%)	30/50 (60%)
POLY-3 RATE (b)	43/47.38	30/43.98
POLY-3 PERCENT (g)	90.8%	68.2%
TERMINAL (d)	19/21 (91%)	19/25 (76%)
FIRST INCIDENCE	320	302
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.003N**
POLY 1.5	P=0.004N**
POLY 6	P=0.004N**
COCH-ARM / FISHERS	P=0.010N**
MAX-ISO-POLY-3	P=0.002N**
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Females

DOSE	0 UG/KG	4600 UG/KG STOP
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**All Organs
 Malignant Tumors**

TUMOR RATES	#	#
OVERALL (a)	15/52 (29%)	37/50 (74%)
POLY-3 RATE (b)	15/38.5	37/44.7
POLY-3 PERCENT (g)	39%	82.8%
TERMINAL (d)	9/21 (43%)	20/25 (80%)
FIRST INCIDENCE	119	545
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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Females

DOSE 0 UG/KG 4600 UG/KG
STOP

All Organs
Malignant and Benign Tumors

TUMOR RATES	#	#
OVERALL (a)	48/52 (92%)	44/50 (88%)
POLY-3 RATE (b)	48/49.26	44/46.95
POLY-3 PERCENT (g)	97.4%	93.7%
TERMINAL (d)	21/21 (100%)	23/25 (92%)
FIRST INCIDENCE	119	302
HC TUMORS SAME RTE	0/0 (0%)	
HC TUMORS ALL RTES	0/0 (0%)	

STATISTICAL TESTS

POLY 3	P=0.323N
POLY 1.5	P=0.378N
POLY 6	P=0.259N
COCH-ARM / FISHERS	P=0.346N
MAX-ISO-POLY-3	P=0.150N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

TDMS No. 20304 - 01
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/SD

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
TEF evaluation (PCB 118)
CAS Number: 31508-00-6

Date Report Requested: 06/26/2008
Time Report Requested: 12:21:48
First Dose M/F: NA / 03/26/04
Lab: BAT

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 ***