

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: 06/24/2008

Time Report Requested: 13:42:49

First Dose M/F: NA / 03/26/04

Lab: BAT

53 Wk_SSAC_R8

C Number: C20304

Lock Date: 10/12/2006

Cage Range: ALL

Date Range: ALL

Reasons For Removal: 25017 SSAC

Removal Date Range: 30-Mar-2005 - 30-Mar-2005

Treatment Groups: Include 001 0 UG/KG

Include 002 10 UG/KG

Include 003 30 UG/KG

Include 004 100 UG/KG

Include 005 220 UG/KG

Include 006 460 UG/KG

Include 007 1000 UG/KG

Include 008 4600 UG/KG

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.**

Liver

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

FEMALE RATS

Organ

Liver
All Organs

Morphology

Cholangiocarcinoma
Malignant Tumors
Malignant and Benign Tumors

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STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(SD)
 LAST REMOVAL AT 53 WEEKS

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

Liver
 Cholangiocarcinoma

TUMOR RATES

OVERALL (a)	0/8 (0%)	0/8 (0%)	0/10 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
POLY-3 RATE (b)	0/8	0/8	0/10	0/8	0/8	0/8
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
INT SACRIFICE 1	0/8 (0%)	0/8 (0%)	0/10 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
HC TUMORS SAME RTE	0/0 (0%)					
HC TUMORS ALL RTES	0/0 (0%)					

STATISTICAL TESTS

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

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STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(SD)
LAST REMOVAL AT 53 WEEKS

Females

DOSE 1000 UG/KG 4600 UG/KG

Liver
Cholangiocarcinoma

TUMOR RATES

OVERALL (a)	0/8 (0%)	3/8 (38%)
POLY-3 RATE (b)	0/8	3/8
POLY-3 PERCENT (g)	0%	37.5%
INT SACRIFICE 1	0/8 (0%)	3/8 (38%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	3/0 (l)
HC TUMORS SAME RTE		
HC TUMORS ALL RTES		

STATISTICAL TESTS

POLY 3	(e)	P=0.086
POLY 1.5	(e)	P=0.086
POLY 6	(e)	P=0.086
COCH-ARM / FISHERS	(e)	P=0.100
MAX-ISO-POLY-3	(e)	P=0.021*
HISTCONT SAME RTE	(e)	(e)
HISTCONT ALL RTES	(e)	(e)

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 LAST REMOVAL AT 53 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

**Mammary Gland
 Fibroadenoma**

TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/8 (0%)	0/8 (0%)	2/10 (20%)	1/8 (13%)	2/8 (25%)	0/8 (0%)
POLY-3 RATE (b)	0/8	0/8	2/10	1/8	2/8	0/8
POLY-3 PERCENT (g)	0%	0%	20%	12.5%	25%	0%
INT SACRIFICE 1	0/8 (0%)	0/8 (0%)	2/10 (20%)	1/8 (13%)	2/8 (25%)	0/8 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	370 (I)	370 (I)	370 (I)	---
HC TUMORS SAME RTE	0/0 (0%)					
HC TUMORS ALL RTEs	0/0 (0%)					

STATISTICAL TESTS

POLY 3	P=0.354N	(e)	P=0.280	P=0.500	P=0.223	(e)
POLY 1.5	P=0.354N	(e)	P=0.280	P=0.500	P=0.223	(e)
POLY 6	P=0.354N	(e)	P=0.280	P=0.500	P=0.223	(e)
COCH-ARM / FISHERS	P=0.354N	(e)	P=0.294	P=0.500	P=0.233	(e)
MAX-ISO-POLY-3	P=0.401	(e)	P=0.103	P=0.158	P=0.064	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(h)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(h)	(h)	(h)	(e)

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LAST REMOVAL AT 53 WEEKS

Females

DOSE 1000 UG/KG 4600 UG/KG

Mammary Gland
Fibroadenoma

TUMOR RATES

	#	#
OVERALL (a)	1/8 (13%)	0/8 (0%)
POLY-3 RATE (b)	1/8	0/8
POLY-3 PERCENT (g)	12.5%	0%
INT SACRIFICE 1	1/8 (13%)	0/8 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	370 (l)	---
HC TUMORS SAME RTE		
HC TUMORS ALL RTES		

STATISTICAL TESTS

POLY 3	P=0.500	(e)
POLY 1.5	P=0.500	(e)
POLY 6	P=0.500	(e)
COCH-ARM / FISHERS	P=0.500	(e)
MAX-ISO-POLY-3	P=0.158	(e)
HISTCONT SAME RTE	(h)	(e)
HISTCONT ALL RTES	(h)	(e)

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 LAST REMOVAL AT 53 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

**All Organs
 Benign Tumors**

TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/8 (13%)	0/8 (0%)	2/10 (20%)	1/8 (13%)	2/8 (25%)	0/8 (0%)
POLY-3 RATE (b)	1/8	0/8	2/10	1/8	2/8	0/8
POLY-3 PERCENT (g)	12.5%	0%	20%	12.5%	25%	0%
INT SACRIFICE 1	1/8 (13%)	0/8 (0%)	2/10 (20%)	1/8 (13%)	2/8 (25%)	0/8 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	370 (I)	---	370 (I)	370 (I)	370 (I)	---
HC TUMORS SAME RTE	0/0 (0%)					
HC TUMORS ALL RTEs	0/0 (0%)					

STATISTICAL TESTS

POLY 3	P=0.671N	P=0.500N	P=0.580	P=0.760	P=0.500	P=0.500N
POLY 1.5	P=0.671N	P=0.500N	P=0.580	P=0.760	P=0.500	P=0.500N
POLY 6	P=0.671N	P=0.500N	P=0.580	P=0.760	P=0.500	P=0.500N
COCH-ARM / FISHERS	P=0.677N	P=0.500N	P=0.588	P=0.767N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.623	P=0.158N	P=0.350	P=1.000	P=0.272	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)

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LAST REMOVAL AT 53 WEEKS

Females

DOSE 1000 UG/KG 4600 UG/KG

All Organs
Benign Tumors

TUMOR RATES	#	#
OVERALL (a)	1/8 (13%)	1/8 (13%)
POLY-3 RATE (b)	1/8	1/8
POLY-3 PERCENT (g)	12.5%	12.5%
INT SACRIFICE 1	1/8 (13%)	1/8 (13%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	370 (I)	370 (I)
HC TUMORS SAME RTE		
HC TUMORS ALL RTES		

STATISTICAL TESTS

POLY 3	P=0.760	P=0.760
POLY 1.5	P=0.760	P=0.760
POLY 6	P=0.760	P=0.760
COCH-ARM / FISHERS	P=0.767N	P=0.767N
MAX-ISO-POLY-3	P=1.000	P=1.000
HISTCONT SAME RTE	(h)	(h)
HISTCONT ALL RTES	(h)	(h)

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 LAST REMOVAL AT 53 WEEKS**

DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

**All Organs
 Malignant Tumors**

TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/8 (0%)	0/8 (0%)	0/10 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
POLY-3 RATE (b)	0/8	0/8	0/10	0/8	0/8	0/8
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
INT SACRIFICE 1	0/8 (0%)	0/8 (0%)	0/10 (0%)	0/8 (0%)	0/8 (0%)	0/8 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
HC TUMORS SAME RTE	0/0 (0%)					
HC TUMORS ALL RTES	0/0 (0%)					

STATISTICAL TESTS

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

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(SD)
 LAST REMOVAL AT 53 WEEKS**

Females

DOSE **1000 UG/KG** **4600 UG/KG**

**All Organs
 Malignant Tumors**

TUMOR RATES	#	#
OVERALL (a)	0/8 (0%)	3/8 (38%)
POLY-3 RATE (b)	0/8	3/8
POLY-3 PERCENT (g)	0%	37.5%
INT SACRIFICE 1	0/8 (0%)	3/8 (38%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	370 (l)
HC TUMORS SAME RTE		
HC TUMORS ALL RTES		

STATISTICAL TESTS

POLY 3	(e)	P=0.086
POLY 1.5	(e)	P=0.086
POLY 6	(e)	P=0.086
COCH-ARM / FISHERS	(e)	P=0.100
MAX-ISO-POLY-3	(e)	P=0.021*
HISTCONT SAME RTE	(e)	(e)
HISTCONT ALL RTES	(e)	(e)

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DOSE	Females					
	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG

**All Organs
 Malignant and Benign Tumors**

TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/8 (13%)	0/8 (0%)	2/10 (20%)	1/8 (13%)	2/8 (25%)	0/8 (0%)
POLY-3 RATE (b)	1/8	0/8	2/10	1/8	2/8	0/8
POLY-3 PERCENT (g)	12.5%	0%	20%	12.5%	25%	0%
INT SACRIFICE 1	1/8 (13%)	0/8 (0%)	2/10 (20%)	1/8 (13%)	2/8 (25%)	0/8 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	370 (I)	---	370 (I)	370 (I)	370 (I)	---
HC TUMORS SAME RTE	0/0 (0%)					
HC TUMORS ALL RTEs	0/0 (0%)					

STATISTICAL TESTS

POLY 3	P=0.013*	P=0.500N	P=0.580	P=0.760	P=0.500	P=0.500N
POLY 1.5	P=0.013*	P=0.500N	P=0.580	P=0.760	P=0.500	P=0.500N
POLY 6	P=0.013*	P=0.500N	P=0.580	P=0.760	P=0.500	P=0.500N
COCH-ARM / FISHERS	P=0.014*	P=0.500N	P=0.588	P=0.767N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.015*	P=0.158N	P=0.350	P=1.000	P=0.272	P=0.158N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)	(e)	(e)

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STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(SD)
LAST REMOVAL AT 53 WEEKS

Females

DOSE 1000 UG/KG 4600 UG/KG

All Organs
Malignant and Benign Tumors

TUMOR RATES	#	#
OVERALL (a)	1/8 (13%)	4/8 (50%)
POLY-3 RATE (b)	1/8	4/8
POLY-3 PERCENT (g)	12.5%	50%
INT SACRIFICE 1	1/8 (13%)	4/8 (50%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	370 (I)	370 (I)
HC TUMORS SAME RTE		
HC TUMORS ALL RTES		

STATISTICAL TESTS

POLY 3	P=0.760	P=0.135
POLY 1.5	P=0.760	P=0.135
POLY 6	P=0.760	P=0.135
COCH-ARM / FISHERS	P=0.767N	P=0.141
MAX-ISO-POLY-3	P=1.000	P=0.050*
HISTCONT SAME RTE	(e)	(e)
HISTCONT ALL RTES	(e)	(e)

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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 ***