

**TDMS No.** 20101 - 02  
**Test Type:** 26-39 WEEKS  
**Route:** DOSED FEED  
**Species/Strain:** MICE/P53(C57BL/6)

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Senna (powdered)  
**CAS Number:** 8013-11-4

**Date Report Requested:** 09/29/2009  
**Time Report Requested:** 09:44:50  
**First Dose M/F:** 06/26/07 / 06/25/07  
**Lab:** BAT

F1\_MD

**C Number:** C20101B  
**Lock Date:** 09/03/2008  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.1.0

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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 Medulla

Heart

Liver

Lung

Nose

Ovary

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF SENNA (POWDERED)**

**MALE MICE**

**Organ**

Bone

Liver

All Organs

**Morphology**

Osteosarcoma

Osteosarcoma or Osteoma

Hepatocellular Adenoma

Osteosarcoma

Osteosarcoma or Osteoma

Benign Tumors

Malignant and Benign Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(P53(C57BL/6))  
 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Males					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>Bone</b>						
<b>Osteosarcoma</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	0/25 (0%)	0/25 (0%)	0/25 (0%)	3/25 (12%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (b)	0/25.00	0/24.59	0/25.00	3/25.00	2/24.90	0/24.00
POLY-3 PERCENT (g)	0%	0%	0%	12%	8%	0%
TERMINAL (d)	0/25 (0%)	0/24 (0%)	0/25 (0%)	3/25 (12%)	1/23 (4%)	0/24 (0%)
FIRST INCIDENCE	---	---	---	276 (T)	256	---
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.542N	(e)	(e)	P=0.114	P=0.234	(e)
POLY 1.5	P=0.543N	(e)	(e)	P=0.114	P=0.235	(e)
POLY 6	P=0.540N	(e)	(e)	P=0.114	P=0.233	(e)
COCH-ARM / FISHERS	P=0.526N	(e)	(e)	P=0.117	P=0.245	(e)
MAX-ISO-POLY-3	P=0.178	(e)	(e)	P=0.035*	P=0.074	(e)
HISTCONT SAME RTE	(h)	(e)	(e)	(h)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(e)	(h)	(h)	(e)

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 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Males					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>Bone</b>						
<b>Osteosarcoma or Osteoma</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	0/25 (0%)	0/25 (0%)	1/25 (4%)	3/25 (12%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (b)	0/25.00	0/24.59	1/25.00	3/25.00	2/24.90	0/24.00
POLY-3 PERCENT (g)	0%	0%	4%	12%	8%	0%
TERMINAL (d)	0/25 (0%)	0/24 (0%)	1/25 (4%)	3/25 (12%)	1/23 (4%)	0/24 (0%)
FIRST INCIDENCE	---	---	276 (T)	276 (T)	256	---
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.441N	(e)	P=0.500	P=0.114	P=0.234	(e)
POLY 1.5	P=0.442N	(e)	P=0.500	P=0.114	P=0.235	(e)
POLY 6	P=0.439N	(e)	P=0.500	P=0.114	P=0.233	(e)
COCH-ARM / FISHERS	P=0.425N	(e)	P=0.500	P=0.117	P=0.245	(e)
MAX-ISO-POLY-3	P=0.220	(e)	P=0.158	P=0.035*	P=0.074	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(h)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(h)	(h)	(h)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(P53(C57BL/6))  
 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Males					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>Liver</b>						
<b>Hepatocellular Adenoma</b>						
<b>TUMOR RATES</b>						
OVERALL (a)	1/25 (4%)	0/25 (0%)	5/25 (20%)	0/25 (0%)	2/25 (8%)	1/25 (4%)
POLY-3 RATE (b)	1/25.00	0/24.59	5/25.00	0/25.00	2/24.69	1/24.00
POLY-3 PERCENT (g)	4%	0%	20%	0%	8.1%	4.2%
TERMINAL (d)	1/25 (4%)	0/24 (0%)	5/25 (20%)	0/25 (0%)	2/23 (9%)	1/24 (4%)
FIRST INCIDENCE	276 (T)	---	276 (T)	---	276 (T)	276 (T)
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.490N	P=0.503N	P=0.093	P=0.500N	P=0.496	P=0.751
POLY 1.5	P=0.491N	P=0.502N	P=0.093	P=0.500N	P=0.498	P=0.751
POLY 6	P=0.487N	P=0.505N	P=0.093	P=0.500N	P=0.492	P=0.751
COCH-ARM / FISHERS	P=0.477N	P=0.500N	P=0.095	P=0.500N	P=0.500	P=0.755N
MAX-ISO-POLY-3	P=0.346	P=0.162N	P=0.039*	P=0.158N	P=0.277	P=0.488
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Males					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>All Organs</b>						
<b>Osteosarcoma</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	0/25 (0%)	0/25 (0%)	0/25 (0%)	3/25 (12%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (b)	0/25.00	0/24.59	0/25.00	3/25.00	2/24.90	0/24.00
POLY-3 PERCENT (g)	0%	0%	0%	12%	8%	0%
TERMINAL (d)	0/25 (0%)	0/24 (0%)	0/25 (0%)	3/25 (12%)	1/23 (4%)	0/24 (0%)
FIRST INCIDENCE	---	---	---	276 (T)	256	---
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.542N	(e)	(e)	P=0.114	P=0.234	(e)
POLY 1.5	P=0.543N	(e)	(e)	P=0.114	P=0.235	(e)
POLY 6	P=0.540N	(e)	(e)	P=0.114	P=0.233	(e)
COCH-ARM / FISHERS	P=0.526N	(e)	(e)	P=0.117	P=0.245	(e)
MAX-ISO-POLY-3	P=0.178	(e)	(e)	P=0.035*	P=0.074	(e)
HISTCONT SAME RTE	(h)	(e)	(e)	(h)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(e)	(h)	(h)	(e)

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 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Males					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>All Organs</b>						
<b>Osteosarcoma or Osteoma</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	0/25 (0%)	0/25 (0%)	1/25 (4%)	3/25 (12%)	2/25 (8%)	0/25 (0%)
POLY-3 RATE (b)	0/25.00	0/24.59	1/25.00	3/25.00	2/24.90	0/24.00
POLY-3 PERCENT (g)	0%	0%	4%	12%	8%	0%
TERMINAL (d)	0/25 (0%)	0/24 (0%)	1/25 (4%)	3/25 (12%)	1/23 (4%)	0/24 (0%)
FIRST INCIDENCE	---	---	276 (T)	276 (T)	256	---
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.441N	(e)	P=0.500	P=0.114	P=0.234	(e)
POLY 1.5	P=0.442N	(e)	P=0.500	P=0.114	P=0.235	(e)
POLY 6	P=0.439N	(e)	P=0.500	P=0.114	P=0.233	(e)
COCH-ARM / FISHERS	P=0.425N	(e)	P=0.500	P=0.117	P=0.245	(e)
MAX-ISO-POLY-3	P=0.220	(e)	P=0.158	P=0.035*	P=0.074	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(h)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(h)	(h)	(h)	(e)



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 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Males					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>All Organs</b>						
<b>Benign Tumors</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	2/25 (8%)	0/25 (0%)	7/25 (28%)	0/25 (0%)	3/25 (12%)	1/25 (4%)
POLY-3 RATE (b)	2/25.00	0/24.59	7/25.00	0/25.00	3/24.69	1/24.00
POLY-3 PERCENT (g)	8%	0%	28%	0%	12.2%	4.2%
TERMINAL (d)	2/25 (8%)	0/24 (0%)	7/25 (28%)	0/25 (0%)	3/23 (13%)	1/24 (4%)
FIRST INCIDENCE	276 (T)	---	276 (T)	---	276 (T)	276 (T)
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.302N	P=0.239N	P=0.068	P=0.235N	P=0.494	P=0.514N
POLY 1.5	P=0.303N	P=0.237N	P=0.068	P=0.235N	P=0.497	P=0.514N
POLY 6	P=0.299N	P=0.241N	P=0.068	P=0.235N	P=0.489	P=0.514N
COCH-ARM / FISHERS	P=0.295N	P=0.245N	P=0.069	P=0.245N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.296N	P=0.077N	P=0.031*	P=0.074N	P=0.317	P=0.295N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Males					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>All Organs</b>						
<b>Malignant Tumors</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	1/25 (4%)	1/25 (4%)	1/25 (4%)	3/25 (12%)	3/25 (12%)	0/25 (0%)
POLY-3 RATE (b)	1/25.00	1/25.00	1/25.00	3/25.00	3/24.90	0/24.00
POLY-3 PERCENT (g)	4%	4%	4%	12%	12.1%	0%
TERMINAL (d)	1/25 (4%)	0/24 (0%)	1/25 (4%)	3/25 (12%)	2/23 (9%)	0/24 (0%)
FIRST INCIDENCE	276 (T)	231	276 (T)	276 (T)	256	---
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.311N	P=0.760	P=0.760	P=0.303	P=0.301	P=0.508N
POLY 1.5	P=0.310N	P=0.760	P=0.760	P=0.303	P=0.302	P=0.508N
POLY 6	P=0.311N	P=0.760	P=0.760	P=0.303	P=0.300	P=0.508N
COCH-ARM / FISHERS	P=0.290N	P=0.755N	P=0.755N	P=0.305	P=0.305	P=0.500N
MAX-ISO-POLY-3	P=0.282N	P=1.000	P=1.000	P=0.150	P=0.149	P=0.168N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Males					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>All Organs</b>						
<b>Malignant and Benign Tumors</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	3/25 (12%)	1/25 (4%)	8/25 (32%)	3/25 (12%)	5/25 (20%)	1/25 (4%)
POLY-3 RATE (b)	3/25.00	1/25.00	8/25.00	3/25.00	5/24.90	1/24.00
POLY-3 PERCENT (g)	12%	4%	32%	12%	20.1%	4.2%
TERMINAL (d)	3/25 (12%)	0/24 (0%)	8/25 (32%)	3/25 (12%)	4/23 (17%)	1/24 (4%)
FIRST INCIDENCE	276 (T)	231	276 (T)	276 (T)	256	276 (T)
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.152N	P=0.303N	P=0.084	P=0.665	P=0.349	P=0.318N
POLY 1.5	P=0.151N	P=0.303N	P=0.084	P=0.665	P=0.351	P=0.317N
POLY 6	P=0.152N	P=0.303N	P=0.084	P=0.665	P=0.347	P=0.318N
COCH-ARM / FISHERS	P=0.138N	P=0.305N	P=0.085	P=0.666N	P=0.351	P=0.305N
MAX-ISO-POLY-3	P=0.219N	P=0.150N	P=0.042*	P=1.000	P=0.221	P=0.165N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(P53(C57BL/6))  
 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Females					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>Bone</b>						
<b>Osteosarcoma</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	2/25 (8%)	2/25 (8%)	1/25 (4%)	3/25 (12%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (b)	2/24.92	2/24.86	1/24.72	3/25.00	0/23.09	2/25.00
POLY-3 PERCENT (g)	8%	8.1%	4.1%	12%	0%	8%
TERMINAL (d)	1/23 (4%)	1/23 (4%)	0/23 (0%)	0/22 (0%)	0/22 (0%)	1/24 (4%)
FIRST INCIDENCE	225	221	232	204	---	264
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.611N	P=0.694	P=0.503N	P=0.502	P=0.253N	P=0.694N
POLY 1.5	P=0.611N	P=0.695	P=0.502N	P=0.501	P=0.249N	P=0.695N
POLY 6	P=0.610N	P=0.694	P=0.505N	P=0.503	P=0.254N	P=0.693N
COCH-ARM / FISHERS	P=0.609N	P=0.695N	P=0.500N	P=0.500	P=0.245N	P=0.695N
MAX-ISO-POLY-3	P=0.537N	P=0.499	P=0.282N	P=0.323	P=0.090N	P=0.498N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Females					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>Bone</b>						
<b>Osteosarcoma or Osteoma</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	2/25 (8%)	2/25 (8%)	1/25 (4%)	3/25 (12%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (b)	2/24.92	2/24.86	1/24.72	3/25.00	0/23.09	2/25.00
POLY-3 PERCENT (g)	8%	8.1%	4.1%	12%	0%	8%
TERMINAL (d)	1/23 (4%)	1/23 (4%)	0/23 (0%)	0/22 (0%)	0/22 (0%)	1/24 (4%)
FIRST INCIDENCE	225	221	232	204	---	264
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.611N	P=0.694	P=0.503N	P=0.502	P=0.253N	P=0.694N
POLY 1.5	P=0.611N	P=0.695	P=0.502N	P=0.501	P=0.249N	P=0.695N
POLY 6	P=0.610N	P=0.694	P=0.505N	P=0.503	P=0.254N	P=0.693N
COCH-ARM / FISHERS	P=0.609N	P=0.695N	P=0.500N	P=0.500	P=0.245N	P=0.695N
MAX-ISO-POLY-3	P=0.537N	P=0.499	P=0.282N	P=0.323	P=0.090N	P=0.498N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)

TDMS No. 20101 - 02  
 Test Type: 26-39 WEEKS  
 Route: DOSED FEED  
 Species/Strain: MICE/P53(C57BL/6)

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Senna (powdered)  
 CAS Number: 8013-11-4

Date Report Requested: 09/29/2009  
 Time Report Requested: 09:44:50  
 First Dose M/F: 06/26/07 / 06/25/07  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(P53(C57BL/6))  
 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Females					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>Liver</b>						
<b>Hepatocellular Adenoma</b>						
<b>TUMOR RATES</b>						
OVERALL (a)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)
POLY-3 RATE (b)	0/24.46	0/24.37	0/24.32	0/23.37	0/23.09	0/24.89
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/23 (0%)	0/23 (0%)	0/23 (0%)	0/22 (0%)	0/22 (0%)	0/24 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)	(e)	(e)

TDMS No. 20101 - 02  
 Test Type: 26-39 WEEKS  
 Route: DOSED FEED  
 Species/Strain: MICE/P53(C57BL/6)

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Senna (powdered)  
 CAS Number: 8013-11-4

Date Report Requested: 09/29/2009  
 Time Report Requested: 09:44:50  
 First Dose M/F: 06/26/07 / 06/25/07  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(P53(C57BL/6))  
 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Females					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>All Organs</b>						
<b>Osteosarcoma</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	2/25 (8%)	2/25 (8%)	1/25 (4%)	3/25 (12%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (b)	2/24.92	2/24.86	1/24.72	3/25.00	0/23.09	2/25.00
POLY-3 PERCENT (g)	8%	8.1%	4.1%	12%	0%	8%
TERMINAL (d)	1/23 (4%)	1/23 (4%)	0/23 (0%)	0/22 (0%)	0/22 (0%)	1/24 (4%)
FIRST INCIDENCE	225	221	232	204	---	264
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.611N	P=0.694	P=0.503N	P=0.502	P=0.253N	P=0.694N
POLY 1.5	P=0.611N	P=0.695	P=0.502N	P=0.501	P=0.249N	P=0.695N
POLY 6	P=0.610N	P=0.694	P=0.505N	P=0.503	P=0.254N	P=0.693N
COCH-ARM / FISHERS	P=0.609N	P=0.695N	P=0.500N	P=0.500	P=0.245N	P=0.695N
MAX-ISO-POLY-3	P=0.537N	P=0.499	P=0.282N	P=0.323	P=0.090N	P=0.498N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)

TDMS No. 20101 - 02  
 Test Type: 26-39 WEEKS  
 Route: DOSED FEED  
 Species/Strain: MICE/P53(C57BL/6)

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Senna (powdered)  
 CAS Number: 8013-11-4

Date Report Requested: 09/29/2009  
 Time Report Requested: 09:44:50  
 First Dose M/F: 06/26/07 / 06/25/07  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(P53(C57BL/6))  
 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Females					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>All Organs</b>						
<b>Osteosarcoma or Osteoma</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	2/25 (8%)	2/25 (8%)	1/25 (4%)	3/25 (12%)	0/25 (0%)	2/25 (8%)
POLY-3 RATE (b)	2/24.92	2/24.86	1/24.72	3/25.00	0/23.09	2/25.00
POLY-3 PERCENT (g)	8%	8.1%	4.1%	12%	0%	8%
TERMINAL (d)	1/23 (4%)	1/23 (4%)	0/23 (0%)	0/22 (0%)	0/22 (0%)	1/24 (4%)
FIRST INCIDENCE	225	221	232	204	---	264
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.611N	P=0.694	P=0.503N	P=0.502	P=0.253N	P=0.694N
POLY 1.5	P=0.611N	P=0.695	P=0.502N	P=0.501	P=0.249N	P=0.695N
POLY 6	P=0.610N	P=0.694	P=0.505N	P=0.503	P=0.254N	P=0.693N
COCH-ARM / FISHERS	P=0.609N	P=0.695N	P=0.500N	P=0.500	P=0.245N	P=0.695N
MAX-ISO-POLY-3	P=0.537N	P=0.499	P=0.282N	P=0.323	P=0.090N	P=0.498N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)



TDMS No. 20101 - 02  
 Test Type: 26-39 WEEKS  
 Route: DOSED FEED  
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P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Senna (powdered)  
 CAS Number: 8013-11-4

Date Report Requested: 09/29/2009  
 Time Report Requested: 09:44:50  
 First Dose M/F: 06/26/07 / 06/25/07  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(P53(C57BL/6))  
 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Females					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>All Organs</b>						
<b>Benign Tumors</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	2/25 (8%)	0/25 (0%)	1/25 (4%)	0/25 (0%)	1/25 (4%)	0/25 (0%)
POLY-3 RATE (b)	2/24.46	0/24.37	1/24.32	0/23.37	1/23.09	0/24.89
POLY-3 PERCENT (g)	8.2%	0%	4.1%	0%	4.3%	0%
TERMINAL (d)	2/23 (9%)	0/23 (0%)	1/23 (4%)	0/22 (0%)	1/22 (5%)	0/24 (0%)
FIRST INCIDENCE	275 (T)	---	275 (T)	---	275 (T)	---
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.337N	P=0.236N	P=0.502N	P=0.245N	P=0.520N	P=0.231N
POLY 1.5	P=0.341N	P=0.235N	P=0.501N	P=0.241N	P=0.518N	P=0.233N
POLY 6	P=0.332N	P=0.236N	P=0.504N	P=0.250N	P=0.519N	P=0.229N
COCH-ARM / FISHERS	P=0.345N	P=0.245N	P=0.500N	P=0.245N	P=0.500N	P=0.245N
MAX-ISO-POLY-3	P=0.072N	P=0.074N	P=0.281N	P=0.083N	P=0.301N	P=0.074N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)

TDMS No. 20101 - 02  
 Test Type: 26-39 WEEKS  
 Route: DOSED FEED  
 Species/Strain: MICE/P53(C57BL/6)

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Senna (powdered)  
 CAS Number: 8013-11-4

Date Report Requested: 09/29/2009  
 Time Report Requested: 09:44:50  
 First Dose M/F: 06/26/07 / 06/25/07  
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(P53(C57BL/6))  
 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Females					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>All Organs</b>						
<b>Malignant Tumors</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	4/25 (16%)	3/25 (12%)	2/25 (8%)	4/25 (16%)	1/25 (4%)	3/25 (12%)
POLY-3 RATE (b)	4/25.00	3/25.00	2/25.00	4/25.00	1/23.15	3/25.00
POLY-3 PERCENT (g)	16%	12%	8%	16%	4.3%	12%
TERMINAL (d)	2/23 (9%)	1/23 (4%)	0/23 (0%)	1/22 (5%)	0/22 (0%)	2/24 (8%)
FIRST INCIDENCE	225	221	232	204	269	264
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.524N	P=0.500N	P=0.334N	P=0.647	P=0.197N	P=0.500N
POLY 1.5	P=0.522N	P=0.500N	P=0.334N	P=0.647	P=0.192N	P=0.500N
POLY 6	P=0.524N	P=0.500N	P=0.334N	P=0.647	P=0.199N	P=0.500N
COCH-ARM / FISHERS	P=0.517N	P=0.500N	P=0.334N	P=0.649N	P=0.174N	P=0.500N
MAX-ISO-POLY-3	P=0.368N	P=0.344N	P=0.194N	P=1.000	P=0.101N	P=0.344N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)

TDMS No. 20101 - 02  
 Test Type: 26-39 WEEKS  
 Route: DOSED FEED  
 Species/Strain: MICE/P53(C57BL/6)

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Senna (powdered)  
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 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(P53(C57BL/6))  
 TERMINAL SACRIFICE AT 40 WEEKS**

DOSE	Females					
	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>All Organs</b>						
<b>Malignant and Benign Tumors</b>						
<b>TUMOR RATES</b>	#	#	#	#	#	#
OVERALL (a)	6/25 (24%)	3/25 (12%)	3/25 (12%)	4/25 (16%)	2/25 (8%)	3/25 (12%)
POLY-3 RATE (b)	6/25.00	3/25.00	3/25.00	4/25.00	2/23.15	3/25.00
POLY-3 PERCENT (g)	24%	12%	12%	16%	8.6%	12%
TERMINAL (d)	4/23 (17%)	1/23 (4%)	1/23 (4%)	1/22 (5%)	1/22 (5%)	2/24 (8%)
FIRST INCIDENCE	225	221	232	204	269	264
HC TUMORS SAME ROUTE	0/0 (0%)					
HC TUMORS ALL ROUTES	0/0 (0%)					
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.360N	P=0.233N	P=0.233N	P=0.364N	P=0.149N	P=0.233N
POLY 1.5	P=0.359N	P=0.233N	P=0.233N	P=0.364N	P=0.143N	P=0.233N
POLY 6	P=0.360N	P=0.233N	P=0.233N	P=0.364N	P=0.151N	P=0.233N
COCH-ARM / FISHERS	P=0.353N	P=0.232N	P=0.232N	P=0.363N	P=0.123N	P=0.232N
MAX-ISO-POLY-3	P=0.156N	P=0.135N	P=0.135N	P=0.242N	P=0.084N	P=0.135N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)	(h)	(h)

TDMS No. 20101 - 02

Test Type: 26-39 WEEKS

Route: DOSED FEED

Species/Strain: MICE/P53(C57BL/6)

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Senna (powdered)

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First Dose M/F: 06/26/07 / 06/25/07

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 \*\*\*