Custom Report - Uterine Sections

NTP Study Number:	C20320		
Lock Date:	03/24/2011		
Cage Range:	ALL		
Date Range:	ALL		
Reasons For Removal:	25021 TSAC	25020 NATD	25019 MSAC
	25018 DACC		
Removal Date Range:	ALL		
Treatment Groups:	Include 002 0 mg/kg	Include 004 250 mg/kg	Include 006 500 mg/kg
	Include 008 1000 mg/kg		
Study Gender:	Both		
TDMSE Version:	2.5.0.0_custom		
PWG Approval Date:	01/08/2013		

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF TETRABROMOBISPHENOL A

FEMALE RATS

Organ	Morphology
Uterus (Original Sections)	Adenocarcinoma
	Adenoma
	Adenoma, Adenocarcinoma, or MMMT
	Malignant Mixed Mullerian Tumor
Uterus (Original or Residual Sections)	Adenocarcinoma
	Adenoma, Adenocarcinoma, or MMMT
	Malignant Mixed Mullerian Tumor
Uterus (Residual Sections)	Adenocarcinoma
	Adenoma, Adenocarcinoma, or MMMT
Uterus, Cervix (Residual Sections)	Sarcoma Stromal

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original Sections)				
Adenocarcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	8/50 (16%)	9/50 (18%)
POLY-3 RATE (b)	3/42.86	3/44.63	8/40.35	9/42.98
POLY-3 PERCENT (g)	7%	6.7%	19.8%	20.9%
TERMINAL (d)	2/34 (6%)	0/34 (0%)	4/29 (14%)	5/33 (15%)
FIRST INCIDENCE	713	548	321	607
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.016*	P=0.644N	P=0.078	P=0.058
POLY 1.5	P=0.017*	P=0.650N	P=0.085	P=0.059
POLY 6	P=0.015*	P=0.640N	P=0.072	P=0.058
COCH-ARM / FISHERS	P=0.020*	P=0.661N	P=0.100	P=0.061
MAX-ISO-POLY-3	P=0.024*	P=0.479N	P=0.045*	P=0.030*

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Residual Sections)				
Adenocarcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	9/50 (18%)	15/50 (30%)	15/50 (30%)
POLY-3 RATE (b)	4/42.86	9/45.34	15/41.19	15/44.37
POLY-3 PERCENT (g)	9.3%	19.9%	36.4%	33.8%
TERMINAL (d)	3/34 (9%)	4/34 (12%)	9/29 (31%)	10/33 (30%)
FIRST INCIDENCE	713	548	321	442
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.003**	P=0.137	P=0.002**	P=0.005**
POLY 1.5	P=0.003**	P=0.129	P=0.003**	P=0.004**
POLY 6	P=0.003**	P=0.145	P=0.002**	P=0.005**
COCH-ARM / FISHERS	P=0.004**	P=0.117	P=0.005**	P=0.005**
MAX-ISO-POLY-3	P=0.004**	P=0.087	P<0.001**	P=0.002**

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original or Residual Sections)				
Adenocarcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	10/50 (20%)	15/50 (30%)	16/50 (32%)
POLY-3 RATE (b)	4/42.86	10/45.40	15/41.19	16/44.53
POLY-3 PERCENT (g)	9.3%	22%	36.4%	35.9%
TERMINAL (d)	3/34 (9%)	4/34 (12%)	9/29 (31%)	10/33 (30%)
FIRST INCIDENCE	713	548	321	442
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.002**	P=0.089	P=0.002**	P=0.002**
POLY 1.5	P=0.002**	P=0.083	P=0.003**	P=0.002**
POLY 6	P=0.002**	P=0.095	P=0.002**	P=0.002**
COCH-ARM / FISHERS	P=0.003**	P=0.074	P=0.005**	P=0.003**
MAX-ISO-POLY-3	P=0.003**	P=0.055	P<0.001**	P<0.001**

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original Sections)				
Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	0/42.80	0/43.51	3/38.34	4/42.37
POLY-3 PERCENT (g)	0%	0%	7.8%	9.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	3/29 (10%)	2/33 (6%)
FIRST INCIDENCE	---	---	728 (T)	625
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.010**	(e)	P=0.100	P=0.059
POLY 1.5	P=0.010**	(e)	P=0.107	P=0.059
POLY 6	P=0.009**	(e)	P=0.093	P=0.057
COCH-ARM / FISHERS	P=0.011*	(e)	P=0.121	P=0.059
MAX-ISO-POLY-3	P=0.015*	(e)	P=0.037*	P=0.019*

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Residual Sections)				
Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	3/43.04	2/44.08	1/38.34	3/42.98
POLY-3 PERCENT (g)	7%	4.5%	2.6%	7%
TERMINAL (d)	1/34 (3%)	1/34 (3%)	1/29 (3%)	1/33 (3%)
FIRST INCIDENCE	668	548	728 (T)	442
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.556	P=0.489N	P=0.347N	P=0.662
POLY 1.5	P=0.561	P=0.492N	P=0.331N	P=0.662N
POLY 6	P=0.550	P=0.491N	P=0.367N	P=0.657
COCH-ARM / FISHERS	P=0.569	P=0.500N	P=0.309N	P=0.661N
MAX-ISO-POLY-3	P=0.516	P=0.316N	P=0.197N	P=0.499

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original or Residual Sections)				
Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	4/50 (8%)	6/50 (12%)
POLY-3 RATE (b)	3/43.04	2/44.08	4/38.34	6/43.15
POLY-3 PERCENT (g)	7%	4.5%	10.4%	13.9%
TERMINAL (d)	1/34 (3%)	1/34 (3%)	4/29 (14%)	3/33 (9%)
FIRST INCIDENCE	668	548	728 (T)	442
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.103	P=0.489N	P=0.437	P=0.242
POLY 1.5	P=0.106	P=0.492N	P=0.461	P=0.243
POLY 6	P=0.100	P=0.491N	P=0.410	P=0.238
COCH-ARM / FISHERS	P=0.110	P=0.500N	P=0.500	P=0.243
MAX-ISO-POLY-3	P=0.141	P=0.316N	P=0.301	P=0.146

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original Sections)				
Adenoma, Adenocarcinoma, or MMMT				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	7/50 (14%)	11/50 (22%)	13/50 (26%)
POLY-3 RATE (b)	3/42.86	7/45.40	11/40.35	13/43.52
POLY-3 PERCENT (g)	7%	15.4%	27.3%	29.9%
TERMINAL (d)	2/34 (6%)	1/34 (3%)	7/29 (24%)	7/33 (21%)
FIRST INCIDENCE	713	548	321	607
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.003**	P=0.181	P=0.013*	P=0.005**
POLY 1.5	P=0.003**	P=0.172	P=0.015*	P=0.005**
POLY 6	P=0.003**	P=0.191	P=0.011*	P=0.006**
COCH-ARM / FISHERS	P=0.005**	P=0.159	P=0.020*	P=0.006**
MAX-ISO-POLY-3	P=0.005**	P=0.112	P=0.007**	P=0.002**

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Residual Sections)				
Adenoma, Adenocarcinoma, or MMMT				
TUMOR RATES	#	#	#	#
OVERALL (a)	6/50 (12%)	10/50 (20%)	16/50 (32%)	16/50 (32%)
POLY-3 RATE (b)	6/43.10	10/45.34	16/41.19	16/44.73
POLY-3 PERCENT (g)	13.9%	22.1%	38.8%	35.8%
TERMINAL (d)	3/34 (9%)	5/34 (15%)	10/29 (35%)	10/33 (30%)
FIRST INCIDENCE	668	548	321	442
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.008**	P=0.237	P=0.007**	P=0.015*
POLY 1.5	P=0.008**	P=0.226	P=0.009**	P=0.014*
POLY 6	P=0.008**	P=0.247	P=0.006**	P=0.015*
COCH-ARM / FISHERS	P=0.009**	P=0.207	P=0.014*	P=0.014*
MAX-ISO-POLY-3	P=0.010**	P=0.167	P=0.004**	P=0.009**

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original or Residual Sections)				
Adenoma, Adenocarcinoma, or MMMT				
TUMOR RATES	#	#	#	#
OVERALL (a)	6/50 (12%)	11/50 (22%)	16/50 (32%)	19/50 (38%)
POLY-3 RATE (b)	6/43.10	11/45.40	16/41.19	19/45.07
POLY-3 PERCENT (g)	13.9%	24.2%	38.8%	42.2%
TERMINAL (d)	3/34 (9%)	5/34 (15%)	10/29 (35%)	11/33 (33%)
FIRST INCIDENCE	668	548	321	442
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.168	P=0.007**	P=0.002**
POLY 1.5	P<0.001**	P=0.159	P=0.009**	P=0.002**
POLY 6	P<0.001**	P=0.177	P=0.006**	P=0.003**
COCH-ARM / FISHERS	P=0.002**	P=0.143	P=0.014*	P=0.002**
MAX-ISO-POLY-3	P=0.002**	P=0.114	P=0.004**	P<0.001**

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original Sections)				
Leiomyosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.80	1/44.13	0/38.34	0/41.83
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	527	---	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.573N	P=0.506	(e)	(e)
POLY 1.5	P=0.570N	P=0.504	(e)	(e)
POLY 6	P=0.578N	P=0.506	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.400N	P=0.166	(e)	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original or Residual Sections)				
Leiomyosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.80	1/44.13	0/38.34	0/41.83
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	527	---	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.573N	P=0.506	(e)	(e)
POLY 1.5	P=0.570N	P=0.504	(e)	(e)
POLY 6	P=0.578N	P=0.506	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.400N	P=0.166	(e)	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original Sections)				
Malignant Mixed Mullerian Tumor				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	4/50 (8%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.80	4/44.28	0/38.34	2/42.23
POLY-3 PERCENT (g)	0%	9%	0%	4.7%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/29 (0%)	1/33 (3%)
FIRST INCIDENCE	---	656	---	615
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.433	P=0.064	(e)	P=0.234
POLY 1.5	P=0.437	P=0.063	(e)	P=0.235
POLY 6	P=0.425	P=0.065	(e)	P=0.231
COCH-ARM / FISHERS	P=0.444	P=0.059	(e)	P=0.247
MAX-ISO-POLY-3	P=0.181	P=0.023*	(e)	P=0.076

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Residual Sections)				
Malignant Mixed Mullerian Tumor				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.80	0/43.51	0/38.34	1/42.23
POLY-3 PERCENT (g)	0%	0%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	615
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.196	(e)	(e)	P=0.497
POLY 1.5	P=0.197	(e)	(e)	P=0.498
POLY 6	P=0.195	(e)	(e)	P=0.495
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.123	(e)	(e)	P=0.158

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original or Residual Sections)				
Malignant Mixed Mullerian Tumor				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	4/50 (8%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.80	4/44.28	0/38.34	2/42.23
POLY-3 PERCENT (g)	0%	9%	0%	4.7%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/29 (0%)	1/33 (3%)
FIRST INCIDENCE	---	656	---	615
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.433	P=0.064	(e)	P=0.234
POLY 1.5	P=0.437	P=0.063	(e)	P=0.235
POLY 6	P=0.425	P=0.065	(e)	P=0.231
COCH-ARM / FISHERS	P=0.444	P=0.059	(e)	P=0.247
MAX-ISO-POLY-3	P=0.181	P=0.023*	(e)	P=0.076

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original Sections)				
Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	4/50 (8%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/42.80	4/43.65	3/38.34	1/42.23
POLY-3 PERCENT (g)	4.7%	9.2%	7.8%	2.4%
TERMINAL (d)	2/34 (6%)	3/34 (9%)	3/29 (10%)	0/33 (0%)
FIRST INCIDENCE	728 (T)	693	728 (T)	614
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.304N	P=0.346	P=0.450	P=0.505N
POLY 1.5	P=0.300N	P=0.344	P=0.469	P=0.503N
POLY 6	P=0.311N	P=0.344	P=0.429	P=0.509N
COCH-ARM / FISHERS	P=0.292N	P=0.339	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.279N	P=0.209	P=0.290	P=0.286N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Residual Sections)				
Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	7/50 (14%)	8/50 (16%)	8/50 (16%)
POLY-3 RATE (b)	5/42.81	7/43.98	8/39.09	8/43.36
POLY-3 PERCENT (g)	11.7%	15.9%	20.5%	18.5%
TERMINAL (d)	4/34 (12%)	5/34 (15%)	6/29 (21%)	5/33 (15%)
FIRST INCIDENCE	725	636	607	442
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.241	P=0.398	P=0.216	P=0.282
POLY 1.5	P=0.242	P=0.393	P=0.237	P=0.280
POLY 6	P=0.238	P=0.399	P=0.197	P=0.281
COCH-ARM / FISHERS	P=0.245	P=0.380	P=0.277	P=0.277
MAX-ISO-POLY-3	P=0.269	P=0.288	P=0.148	P=0.192

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original or Residual Sections)				
Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	9/50 (18%)	9/50 (18%)	8/50 (16%)
POLY-3 RATE (b)	5/42.81	9/43.98	9/39.09	8/43.36
POLY-3 PERCENT (g)	11.7%	20.5%	23%	18.5%
TERMINAL (d)	4/34 (12%)	7/34 (21%)	7/29 (24%)	5/33 (15%)
FIRST INCIDENCE	725	636	607	442
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.307	P=0.206	P=0.141	P=0.282
POLY 1.5	P=0.308	P=0.202	P=0.159	P=0.280
POLY 6	P=0.304	P=0.206	P=0.126	P=0.281
COCH-ARM / FISHERS	P=0.310	P=0.194	P=0.194	P=0.277
MAX-ISO-POLY-3	P=0.226	P=0.135	P=0.095	P=0.192

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original Sections)				
Sarcoma Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.80	2/43.91	0/38.34	1/42.00
POLY-3 PERCENT (g)	0%	4.6%	0%	2.4%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	614	---	686
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.530	P=0.243	(e)	P=0.496
POLY 1.5	P=0.534	P=0.241	(e)	P=0.498
POLY 6	P=0.523	P=0.243	(e)	P=0.493
COCH-ARM / FISHERS	P=0.539	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.326	P=0.081	(e)	P=0.158

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original or Residual Sections)				
Sarcoma Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.80	2/43.91	0/38.34	1/42.00
POLY-3 PERCENT (g)	0%	4.6%	0%	2.4%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	614	---	686
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.530	P=0.243	(e)	P=0.496
POLY 1.5	P=0.534	P=0.241	(e)	P=0.498
POLY 6	P=0.523	P=0.243	(e)	P=0.493
COCH-ARM / FISHERS	P=0.539	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.326	P=0.081	(e)	P=0.158

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original Sections)				
Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	6/50 (12%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	2/42.80	6/44.05	3/38.34	2/42.40
POLY-3 PERCENT (g)	4.7%	13.6%	7.8%	4.7%
TERMINAL (d)	2/34 (6%)	4/34 (12%)	3/29 (10%)	0/33 (0%)
FIRST INCIDENCE	728 (T)	614	728 (T)	614
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.381N	P=0.141	P=0.450	P=0.691
POLY 1.5	P=0.376N	P=0.139	P=0.469	P=0.692
POLY 6	P=0.389N	P=0.142	P=0.429	P=0.688
COCH-ARM / FISHERS	P=0.367N	P=0.134	P=0.500	P=0.691N
MAX-ISO-POLY-3	P=0.353N	P=0.077	P=0.290	P=0.495

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Residual Sections)				
Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	7/50 (14%)	8/50 (16%)	8/50 (16%)
POLY-3 RATE (b)	5/42.81	7/43.98	8/39.09	8/43.36
POLY-3 PERCENT (g)	11.7%	15.9%	20.5%	18.5%
TERMINAL (d)	4/34 (12%)	5/34 (15%)	6/29 (21%)	5/33 (15%)
FIRST INCIDENCE	725	636	607	442
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.241	P=0.398	P=0.216	P=0.282
POLY 1.5	P=0.242	P=0.393	P=0.237	P=0.280
POLY 6	P=0.238	P=0.399	P=0.197	P=0.281
COCH-ARM / FISHERS	P=0.245	P=0.380	P=0.277	P=0.277
MAX-ISO-POLY-3	P=0.269	P=0.288	P=0.148	P=0.192

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus (Original or Residual Sections)				
Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	11/50 (22%)	9/50 (18%)	9/50 (18%)
POLY-3 RATE (b)	5/42.81	11/44.38	9/39.09	9/43.52
POLY-3 PERCENT (g)	11.7%	24.8%	23%	20.7%
TERMINAL (d)	4/34 (12%)	8/34 (24%)	7/29 (24%)	5/33 (15%)
FIRST INCIDENCE	725	614	607	442
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.281	P=0.094	P=0.141	P=0.199
POLY 1.5	P=0.281	P=0.091	P=0.159	P=0.197
POLY 6	P=0.279	P=0.097	P=0.126	P=0.200
COCH-ARM / FISHERS	P=0.283	P=0.086	P=0.194	P=0.194
MAX-ISO-POLY-3	P=0.153	P=0.058	P=0.095	P=0.130

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Residual Sections)				
Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/43.38	1/43.51	2/39.50	1/41.99
POLY-3 PERCENT (g)	2.3%	2.3%	5.1%	2.4%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	545	728 (T)	529	688
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.575	P=0.760N	P=0.467	P=0.754
POLY 1.5	P=0.581	P=0.759N	P=0.479	P=0.756
POLY 6	P=0.566	P=0.759	P=0.455	P=0.749
COCH-ARM / FISHERS	P=0.591	P=0.753N	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.561	P=0.498N	P=0.262	P=0.490

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Original or Residual Sections)				
Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/43.38	1/43.51	2/39.50	1/41.99
POLY-3 PERCENT (g)	2.3%	2.3%	5.1%	2.4%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	545	728 (T)	529	688
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.575	P=0.760N	P=0.467	P=0.754
POLY 1.5	P=0.581	P=0.759N	P=0.479	P=0.756
POLY 6	P=0.566	P=0.759	P=0.455	P=0.749
COCH-ARM / FISHERS	P=0.591	P=0.753N	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.561	P=0.498N	P=0.262	P=0.490

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Original Sections)				
Sarcoma Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.80	0/43.51	1/38.34	0/41.83
POLY-3 PERCENT (g)	0%	0%	2.6%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/29 (3%)	0/33 (0%)
FIRST INCIDENCE	---	---	728 (T)	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.690	(e)	P=0.478	(e)
POLY 1.5	P=0.692	(e)	P=0.486	(e)
POLY 6	P=0.687	(e)	P=0.469	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.372	(e)	P=0.158	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Residual Sections)				
Sarcoma Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.80	0/43.51	0/38.34	2/42.58
POLY-3 PERCENT (g)	0%	0%	0%	4.7%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	545
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.044*	(e)	(e)	P=0.236
POLY 1.5	P=0.044*	(e)	(e)	P=0.236
POLY 6	P=0.043*	(e)	(e)	P=0.234
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.032*	(e)	(e)	P=0.076

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Original or Residual Sections)				
Sarcoma Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/42.80	0/43.51	1/38.34	2/42.58
POLY-3 PERCENT (g)	0%	0%	2.6%	4.7%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/29 (3%)	0/33 (0%)
FIRST INCIDENCE	---	---	728 (T)	545
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.068	(e)	P=0.478	P=0.236
POLY 1.5	P=0.069	(e)	P=0.486	P=0.236
POLY 6	P=0.068	(e)	P=0.469	P=0.234
COCH-ARM / FISHERS	P=0.070	(e)	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.077	(e)	P=0.158	P=0.076

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Original Sections)				
Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.80	0/43.51	1/38.34	0/41.83
POLY-3 PERCENT (g)	0%	0%	2.6%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/29 (3%)	0/33 (0%)
FIRST INCIDENCE	---	---	728 (T)	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.690	(e)	P=0.478	(e)
POLY 1.5	P=0.692	(e)	P=0.486	(e)
POLY 6	P=0.687	(e)	P=0.469	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.372	(e)	P=0.158	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Residual Sections)				
Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	1/43.38	1/43.51	2/39.50	3/42.73
POLY-3 PERCENT (g)	2.3%	2.3%	5.1%	7%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	545	728 (T)	529	545
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.159	P=0.760N	P=0.467	P=0.300
POLY 1.5	P=0.161	P=0.759N	P=0.479	P=0.302
POLY 6	P=0.156	P=0.759	P=0.455	P=0.295
COCH-ARM / FISHERS	P=0.165	P=0.753N	P=0.500	P=0.309
MAX-ISO-POLY-3	P=0.219	P=0.498N	P=0.262	P=0.151

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Original or Residual Sections)				
Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	1/43.38	1/43.51	3/39.50	3/42.73
POLY-3 PERCENT (g)	2.3%	2.3%	7.6%	7%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	1/29 (3%)	0/33 (0%)
FIRST INCIDENCE	545	728 (T)	529	545
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.158	P=0.760N	P=0.272	P=0.300
POLY 1.5	P=0.160	P=0.759N	P=0.284	P=0.302
POLY 6	P=0.155	P=0.759	P=0.260	P=0.295
COCH-ARM / FISHERS	P=0.165	P=0.753N	P=0.309	P=0.309
MAX-ISO-POLY-3	P=0.221	P=0.498N	P=0.142	P=0.151

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Residual Sections)				
Schwannoma Malignant				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.80	0/43.51	1/38.34	0/41.83
POLY-3 PERCENT (g)	0%	0%	2.6%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/29 (3%)	0/33 (0%)
FIRST INCIDENCE	---	---	728 (T)	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.690	(e)	P=0.478	(e)
POLY 1.5	P=0.692	(e)	P=0.486	(e)
POLY 6	P=0.687	(e)	P=0.469	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.372	(e)	P=0.158	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Original or Residual Sections)				
Schwannoma Malignant				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.80	0/43.51	1/38.34	0/41.83
POLY-3 PERCENT (g)	0%	0%	2.6%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/29 (3%)	0/33 (0%)
FIRST INCIDENCE	---	---	728 (T)	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.690	(e)	P=0.478	(e)
POLY 1.5	P=0.692	(e)	P=0.486	(e)
POLY 6	P=0.687	(e)	P=0.469	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.372	(e)	P=0.158	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Original Sections)				
Squamous Cell Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.80	1/43.78	0/38.34	0/41.83
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	656	---	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.574N	P=0.505	(e)	(e)
POLY 1.5	P=0.571N	P=0.503	(e)	(e)
POLY 6	P=0.579N	P=0.504	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.399N	P=0.164	(e)	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Uterus, Cervix (Original or Residual Sections)				
Squamous Cell Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.80	1/43.78	0/38.34	0/41.83
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	656	---	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.574N	P=0.505	(e)	(e)
POLY 1.5	P=0.571N	P=0.503	(e)	(e)
POLY 6	P=0.579N	P=0.504	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.399N	P=0.164	(e)	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Vagina (Original Sections)				
Granular Cell Tumor Malignant				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.80	1/43.51	0/38.34	0/41.83
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	728 (T)	---	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.574N	P=0.503	(e)	(e)
POLY 1.5	P=0.571N	P=0.503	(e)	(e)
POLY 6	P=0.580N	P=0.502	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.398N	P=0.163	(e)	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Vagina (Original or Residual Sections)				
Granular Cell Tumor Malignant				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.80	1/43.51	0/38.34	0/41.83
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	728 (T)	---	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.574N	P=0.503	(e)	(e)
POLY 1.5	P=0.571N	P=0.503	(e)	(e)
POLY 6	P=0.580N	P=0.502	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.398N	P=0.163	(e)	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Vagina (Original Sections)				
Leiomyoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.38	0/43.51	0/38.34	0/41.83
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	545	---	---	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.311N	P=0.499N	P=0.525N	P=0.507N
POLY 1.5	P=0.309N	P=0.499N	P=0.515N	P=0.504N
POLY 6	P=0.311N	P=0.502N	P=0.535N	P=0.512N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.136N	P=0.158N	P=0.188N	P=0.168N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Vagina (Original or Residual Sections)				
Leiomyoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.38	0/43.51	0/38.34	0/41.83
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	545	---	---	---
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.311N	P=0.499N	P=0.525N	P=0.507N
POLY 1.5	P=0.309N	P=0.499N	P=0.515N	P=0.504N
POLY 6	P=0.311N	P=0.502N	P=0.535N	P=0.512N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.136N	P=0.158N	P=0.188N	P=0.168N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Vagina (Original Sections)				
Polyp				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.80	0/43.51	0/38.34	1/42.41
POLY-3 PERCENT (g)	0%	0%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	545
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.197	(e)	(e)	P=0.498
POLY 1.5	P=0.197	(e)	(e)	P=0.499
POLY 6	P=0.195	(e)	(e)	P=0.496
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.124	(e)	(e)	P=0.158

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE	0 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Vagina (Original or Residual Sections)				
Polyp				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.80	0/43.51	0/38.34	1/42.41
POLY-3 PERCENT (g)	0%	0%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/29 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	545
HC TUMORS SAME ROUTE	0/0 (0%)			
HC TUMORS ALL ROUTES	0/0 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.197	(e)	(e)	P=0.498
POLY 1.5	P=0.197	(e)	(e)	P=0.499
POLY 6	P=0.195	(e)	(e)	P=0.496
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.124	(e)	(e)	P=0.158

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)	Historical Controls statistic is not calculated when the HC Poly-3 rate is higher than the Poly-3 rates for all dose groups.
(n)	No statistics are calculated if all dose groups have fewer than two tumors.
(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<=0.05).
**	To the right of any statistical result, indicates significance at (P<=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 ***