

**Experiment Number:** 05069-10  
**Test Type:** CHRONIC  
**Route:** DERMAL,SOLUTION  
**Species/Strain:** Rat/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
**Test Compound:** 1,2-Dihydro-2,2,4-trimethylquinoline (monomer)  
**CAS Number:** 147-47-7

**Date Report Requested:** 10/21/2014  
**Time Report Requested:** 01:39:36  
**First Dose M/F:** NA / NA  
**Lab:** TSI MASON

<b>C Number:</b>	C60902B
<b>Lock Date:</b>	Not Entered.
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

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## HISTORICAL CONTROL STUDIES

From NA 1994 report

### SAME ROUTE

05106-01 -- Diethyl phthalate (SKIN )

05109-11 -- Triethanolamine (SKIN ACETONE)

### ALL ROUTES

05085-01 -- Manganese sulfate monohydrate (ORAL FEED)

05086-01 -- o-Benzyl-p-chlorophenol (GAVAGE CORN OIL)

05087-01 -- Triamterene (ORAL FEED)

05089-01 -- Chloraminated water (ORAL WATER)

05090-01 -- Coumarin (GAVAGE CORN OIL)

05091-01 -- 3,4-Dihydrocoumarin (GAVAGE CORN OIL)

05092-01 -- o-Nitroanisole (ORAL FEED)

05100-03 -- Tricresyl phosphate (ORAL FEED)

05102-05 -- Benzethonium chloride (SKIN ETHANOL)

05106-01 -- Diethyl phthalate (SKIN )

05108-01 -- Promethazine hydrochloride (GAVAGE WATER)

05109-11 -- Triethanolamine (SKIN ACETONE)

05111-01 -- 1,2,3-Trichloropropane (GAVAGE CORN OIL)

05114-01 -- Hexachlorocyclopentadiene (INHALATION AIR)

05120-03 -- Benzyl acetate (ORAL FEED)

05127-01 -- Barium chloride dihydrate (ORAL WATER)

05130-03 -- C.I. Direct blue 218 (ORAL FEED)

05131-01 -- Sodium fluoride (ORAL WATER)

05133-03 -- Acetonitrile (INHALATION AIR)

05142-03 -- tert-Butyl alcohol (ORAL WATER)

05150-01 -- Methylphenidate hydrochloride (ORAL FEED)

05155-03 -- p-Nitrobenzoic acid (ORAL FEED)

05165-01 -- 4,4-Thiobis(6-tert-butyl-m-cresol) (ORAL FEED)

05185-03 -- Isobutyl nitrite (INHALATION AIR)

05214-01 -- 1-trans-delta-9-Tetrahydrocannabinol (GAVAGE CORN OIL)

88034-03 -- Ozone (INHALATION AIR)

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**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES  
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Pituitary Gland

Testes

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RAT(F 344/N)  
 LAST REMOVAL AT 104 WEEKS**

DOSE	MALE		
	0 MG/KG	60 MG/KG	100 MG/KG
<b>Pituitary Gland: Pars Distalis or Unspecified Site</b>			
<b>Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	4/10 (40%)	2/10 (20%)	5/9 (56%)
POLY-3 RATE (b)	4/10.00	2/10.00	5/9.00
POLY-3 PERCENT (g)	40%	20%	55.6%
INT SACRIFICE 1	4/10 (40%)	5/9 (56%)	2/10 (20%)
TERMINAL (d)	4/10 (40%)	2/10 (20%)	5/9 (56%)
FIRST INCIDENCE	458(I)	458(I)	458(I)
HC TUMORS SAME ROUTE	74/94 (79%)		
HC TUMORS ALL ROUTES	524/1317 (40%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.423	P=0.318N	P=0.417
POLY 1.5	P=0.423	P=0.318N	P=0.417
POLY 6	P=0.423	P=0.318N	P=0.417
COCH-ARM / FISHERS	P=0.422	P=0.314N	P=0.414
MAX-ISO-POLY-3	P=0.188	P=0.172N	P=0.263
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	P=0.532	P=1.000	P=0.388
CURR VS HC SAME RTE	P=0.011*		
CURR VS HC ALL RTEs	P=0.953		

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Lab: TSI MASON

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RAT(F 344/N)  
LAST REMOVAL AT 104 WEEKS

DOSE	MALE		
	0 MG/KG	60 MG/KG	100 MG/KG
<b>Testes</b>			
<b>Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL(a)	4/10 (40%)	7/10 (70%)	4/10 (40%)
POLY-3 RATE (b)	4/10.00	7/10.00	4/10.00
POLY-3 PERCENT (g)	40%	70%	40%
INT SACRIFICE 1	4/10 (40%)	4/10 (40%)	7/10 (70%)
TERMINAL (d)	4/10 (40%)	7/10 (70%)	4/10 (40%)
FIRST INCIDENCE	458(l)	458(l)	458(l)
HC TUMORS SAME ROUTE	35/100 (35%)		
HC TUMORS ALL ROUTES	1053/1332 (79%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.535	P=0.186	P=0.667
POLY 1.5	P=0.535	P=0.186	P=0.667
POLY 6	P=0.535	P=0.186	P=0.667
COCH-ARM / FISHERS	P=0.535	P=0.185	P=0.675N
MAX-ISO-POLY-3	P=0.355	P=0.090	P=1.000
HISTCONT SAME RTE	P=0.493	P=0.285	P=1.000
HISTCONT ALL RTEs	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.878		
CURR VS HC ALL RTEs	P=0.000**		

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 Lab: TSI MASON

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RAT(F 344/N)  
 LAST REMOVAL AT 104 WEEKS**

DOSE	MALE		
	0 MG/KG	60 MG/KG	100 MG/KG
<b>All Organs</b>			
<b>Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	8/10 (80%)	8/10 (80%)	8/10 (80%)
POLY-3 RATE (b)	8/10.00	8/10.00	8/10.00
POLY-3 PERCENT (g)	80%	80%	80%
INT SACRIFICE 1	8/10 (80%)	8/10 (80%)	8/10 (80%)
TERMINAL (d)	8/10 (80%)	8/10 (80%)	8/10 (80%)
FIRST INCIDENCE	458(I)	458(I)	458(I)
HC TUMORS SAME ROUTE	89/100 (89%)		
HC TUMORS ALL ROUTES	1252/1339 (94%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.624	P=0.702	P=0.702
POLY 1.5	P=0.624	P=0.702	P=0.702
POLY 6	P=0.624	P=0.702	P=0.702
COCH-ARM / FISHERS	P=0.631	P=0.709N	P=0.709N
MAX-ISO-POLY-3	P=0.668N	P=1.000	P=1.000
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.220		
CURR VS HC ALL RTEs	P=0.007**		

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 First Dose M/F: NA / NA  
 Lab: TSI MASON

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RAT(F 344/N)  
 LAST REMOVAL AT 104 WEEKS**

DOSE	MALE		
	0 MG/KG	60 MG/KG	100 MG/KG
<b>All Organs</b>			
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear or Undifferentiated</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	2/10 (20%)	2/10 (20%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	2/10.00	0/10.00
POLY-3 PERCENT (g)	20%	20%	0%
INT SACRIFICE 1	2/10 (20%)	0/10 (0%)	2/10 (20%)
TERMINAL (d)	2/10 (20%)	2/10 (20%)	0/10 (0%)
FIRST INCIDENCE	458(I)	458(I)	---
HC TUMORS SAME ROUTE	33/100 (33%)		
HC TUMORS ALL ROUTES	614/1339 (46%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.207N	P=0.702	P=0.227N
POLY 1.5	P=0.207N	P=0.702	P=0.227N
POLY 6	P=0.207N	P=0.702	P=0.227N
COCH-ARM / FISHERS	P=0.204N	P=0.709N	P=0.237N
MAX-ISO-POLY-3	P=0.135N	P=1.000	P=0.067N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.508		
CURR VS HC ALL RTEs	P=0.074		

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 Lab: TSI MASON

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RAT(F 344/N)  
 LAST REMOVAL AT 104 WEEKS**

DOSE	MALE		
	0 MG/KG	60 MG/KG	100 MG/KG
<b>All Organs</b>			
<b>Malignant Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	2/10 (20%)	2/10 (20%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	2/10.00	0/10.00
POLY-3 PERCENT (g)	20%	20%	0%
INT SACRIFICE 1	2/10 (20%)	0/10 (0%)	2/10 (20%)
TERMINAL (d)	2/10 (20%)	2/10 (20%)	0/10 (0%)
FIRST INCIDENCE	458(I)	458(I)	---
HC TUMORS SAME ROUTE	43/100 (43%)		
HC TUMORS ALL ROUTES	785/1339 (59%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.207N	P=0.702	P=0.227N
POLY 1.5	P=0.207N	P=0.702	P=0.227N
POLY 6	P=0.207N	P=0.702	P=0.227N
COCH-ARM / FISHERS	P=0.204N	P=0.709N	P=0.237N
MAX-ISO-POLY-3	P=0.135N	P=1.000	P=0.067N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.183		
CURR VS HC ALL RTEs	P=0.008**		



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 Lab: TSI MASON

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RAT(F 344/N)  
 LAST REMOVAL AT 104 WEEKS**

DOSE	MALE		
	0 MG/KG	60 MG/KG	100 MG/KG
<b>All Organs</b>			
<b>Malignant and Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	8/10 (80%)	8/10 (80%)	8/10 (80%)
POLY-3 RATE (b)	8/10.00	8/10.00	8/10.00
POLY-3 PERCENT (g)	80%	80%	80%
INT SACRIFICE 1	8/10 (80%)	8/10 (80%)	8/10 (80%)
TERMINAL (d)	8/10 (80%)	8/10 (80%)	8/10 (80%)
FIRST INCIDENCE	458(I)	458(I)	458(I)
HC TUMORS SAME ROUTE	93/100 (93%)		
HC TUMORS ALL ROUTES	1292/1339 (96%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.624	P=0.702	P=0.702
POLY 1.5	P=0.624	P=0.702	P=0.702
POLY 6	P=0.624	P=0.702	P=0.702
COCH-ARM / FISHERS	P=0.631	P=0.709N	P=0.709N
MAX-ISO-POLY-3	P=0.668N	P=1.000	P=1.000
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.047*		
CURR VS HC ALL RTEs	P=0.000**		

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 Species/Strain: Rat/F 344/N

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RAT(F 344/N)  
 LAST REMOVAL AT 105 WEEKS**

DOSE	FEMALE		
	0 MG/KG	60 MG/KG	100 MG/KG
<b>Pituitary Gland: Pars Distalis or Unspecified Site</b>			
<b>Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	1/10 (10%)	1/10 (10%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	1/10.00	2/10.00
POLY-3 PERCENT (g)	10%	10%	20%
INT SACRIFICE 1	1/10 (10%)	2/10 (20%)	1/10 (10%)
TERMINAL (d)	1/10 (10%)	1/10 (10%)	2/10 (20%)
FIRST INCIDENCE	457(l)	457(l)	457(l)
HC TUMORS SAME ROUTE	71/100 (71%)		
HC TUMORS ALL ROUTES	731/1321 (55%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.417	P=0.760	P=0.500
POLY 1.5	P=0.417	P=0.760	P=0.500
POLY 6	P=0.417	P=0.760	P=0.500
COCH-ARM / FISHERS	P=0.414	P=0.763N	P=0.500
MAX-ISO-POLY-3	P=0.369	P=1.000	P=0.274
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.000**		
CURR VS HC ALL RTEs	P=0.003**		

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RAT(F 344/N)  
 LAST REMOVAL AT 105 WEEKS**

DOSE	FEMALE		
	0 MG/KG	60 MG/KG	100 MG/KG
<b>All Organs</b>			
<b>Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	2/10 (20%)	3/10 (30%)	2/10 (20%)
POLY-3 RATE (b)	2/10.00	3/10.00	2/10.00
POLY-3 PERCENT (g)	20%	30%	20%
INT SACRIFICE 1	2/10 (20%)	2/10 (20%)	3/10 (30%)
TERMINAL (d)	2/10 (20%)	3/10 (30%)	2/10 (20%)
FIRST INCIDENCE	457(I)	457(I)	457(I)
HC TUMORS SAME ROUTE	90/101 (89%)		
HC TUMORS ALL ROUTES	1078/1328 (81%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.592	P=0.500	P=0.702
POLY 1.5	P=0.592	P=0.500	P=0.702
POLY 6	P=0.592	P=0.500	P=0.702
COCH-ARM / FISHERS	P=0.597	P=0.500	P=0.709N
MAX-ISO-POLY-3	P=0.547N	P=0.311	P=1.000
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.000**		
CURR VS HC ALL RTEs	P=0.000**		

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RAT(F 344/N)  
 LAST REMOVAL AT 105 WEEKS**

DOSE	FEMALE		
	0 MG/KG	60 MG/KG	100 MG/KG
<b>All Organs</b>			
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear or Undifferentiated</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	30/101 (30%)		
HC TUMORS ALL ROUTES	370/1328 (28%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)
HISTCONT SAME RTE	(n)	(n)	(n)
HISTCONT ALL RTEs	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)		
CURR VS HC ALL RTEs	(n)		

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RAT(F 344/N)  
 LAST REMOVAL AT 105 WEEKS**

DOSE	FEMALE		
	0 MG/KG	60 MG/KG	100 MG/KG
<b>All Organs</b>			
<b>Malignant Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)	1/10 (10%)
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	457(I)	---
HC TUMORS SAME ROUTE	48/101 (48%)		
HC TUMORS ALL ROUTES	561/1328 (42%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)
HISTCONT SAME RTE	(n)	(n)	(n)
HISTCONT ALL RTEs	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)		
CURR VS HC ALL RTEs	(n)		

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RAT(F 344/N)  
 LAST REMOVAL AT 105 WEEKS**

DOSE	FEMALE		
	0 MG/KG	60 MG/KG	100 MG/KG
<b>All Organs</b>			
<b>Malignant and Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	2/10 (20%)	3/10 (30%)	2/10 (20%)
POLY-3 RATE (b)	2/10.00	3/10.00	2/10.00
POLY-3 PERCENT (g)	20%	30%	20%
INT SACRIFICE 1	2/10 (20%)	2/10 (20%)	3/10 (30%)
TERMINAL (d)	2/10 (20%)	3/10 (30%)	2/10 (20%)
FIRST INCIDENCE	457(l)	457(l)	457(l)
HC TUMORS SAME ROUTE	98/101 (97%)		
HC TUMORS ALL ROUTES	1224/1328 (92%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.592	P=0.500	P=0.702
POLY 1.5	P=0.592	P=0.500	P=0.702
POLY 6	P=0.592	P=0.500	P=0.702
COCH-ARM / FISHERS	P=0.597	P=0.500	P=0.709N
MAX-ISO-POLY-3	P=0.547N	P=0.311	P=1.000
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.000**		
CURR VS HC ALL RTEs	P=0.000**		

**Experiment Number:** 05069-10  
**Test Type:** CHRONIC  
**Route:** DERMAL,SOLUTION  
**Species/Strain:** Rat/F 344/N

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
**Test Compound:** 1,2-Dihydro-2,2,4-trimethylquinoline (monomer)  
**CAS Number:** 147-47-7

**Date Report Requested:** 10/21/2014  
**Time Report Requested:** 01:39:36  
**First Dose M/F:** NA / NA  
**Lab:** TSI MASON

**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.
  - (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 ( $P \leq 0.05$ ).
  - \*\* 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 \*\***