

**Experiment Number:** 20725 - 04  
**Test Type:** CHRONIC  
**Route:** RESPIRATORY EXPOSURE WHOLE BODY  
**Species/Strain:** MICE/B6C3F1

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
2,3-Butanedione  
**CAS Number:** 431-03-8

**Date Report Requested:** 04/15/2016  
**Time Report Requested:** 10:33:42  
**First Dose M/F:** 08/31/09 / 08/31/09  
**Lab:** BNW

F1\_Mice

**NTP Study Number:** C20725  
**Lock Date:** 10/11/2012  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 3.0.2.3\_002  
**PWG Approval Date:** 01/25/2016

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**HISTORICAL CONTROL STUDIES**  
**From July 2015 report**

**SAME ROUTE**

20601-04 -- Antimony trioxide (INHALATION AIR)  
60311-06 -- Cobalt (INHALATION AIR)  
20515-04 -- Metal Working Fluids: CIMSTAR 3800 (INHALATION AIR)  
20523-04 -- Metal Working Fluids: TRIM® VX (INHALATION AIR)  
20303-06 -- Vinylidene Chloride (INHALATION AIR)

**ALL ROUTES**

20601-04 -- Antimony trioxide (INHALATION AIR)  
60311-06 -- Cobalt (INHALATION AIR)  
99031-04 -- Ginkgo biloba extract (GAVAGE CORN OIL)  
20203-04 -- Green Tea Extract (GAVAGE WATER)  
20006-04 -- Indole-3-carbinol (GAVAGE CORN OIL)  
20515-04 -- Metal Working Fluids: CIMSTAR 3800 (INHALATION AIR)  
20523-04 -- Metal Working Fluids: TRIM® VX (INHALATION AIR)  
20209-04 -- Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)] (GAVAGE CORN OIL)  
20320-04 -- Tetrabromobisphenol A (GAVAGE CORN OIL)  
20303-06 -- Vinylidene Chloride (INHALATION AIR)  
96014-06 -- Water disinfection byproducts (Bromodichloroacetic Acid) (ORAL WATER)

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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

Islets, Pancreatic

Liver

Lung

Nose

Ovary

Pituitary Gland

Spleen

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## SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF 2,3-BUTANEDIONE

### MALE MICE

#### Organ

Adrenal Cortex  
Liver

All Organs

#### Morphology

Adenoma  
Hepatocellular Adenoma  
Hepatocellular Carcinoma  
Hepatocellular Carcinoma or Hepatoblastoma  
Hepatocellular Carcinoma or Hepatocellular Adenoma  
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma  
Benign Tumors  
Malignant Tumors  
Malignant and Benign Tumors

### FEMALE MICE

#### Organ

Liver

Lung  
Nose  
Ovary

All Organs

#### Morphology

Hepatocellular Carcinoma  
Hepatocellular Carcinoma or Hepatoblastoma  
Hepatocellular Carcinoma or Hepatocellular Adenoma  
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma  
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma  
Carcinoma  
Cystadenoma  
Luteoma  
Hemangiosarcoma or Hemangioma  
Benign Tumors  
Malignant Tumors  
Malignant and Benign Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Adrenal Cortex</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	8/49 (16%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	2/45.17	8/45.53	3/45.68	2/38.16
POLY-3 PERCENT (g)	4.4%	17.6%	6.6%	5.2%
TERMINAL (d)	1/35 (3%)	7/39 (18%)	3/37 (8%)	2/25 (8%)
FIRST INCIDENCE	590	611	729 (T)	729 (T)
HC TUMORS SAME ROUTE	18/248 (7%)			
HC TUMORS ALL ROUTES	23/547 (4%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.381N	P=0.046*	P=0.505	P=0.632
POLY 1.5	P=0.354N	P=0.044*	P=0.502	P=0.649
POLY 6	P=0.398N	P=0.049*	P=0.511	P=0.618
COCH-ARM / FISHERS	P=0.284N	P=0.043*	P=0.500	P=0.691N
MAX-ISO-POLY-3	P=0.320N	P=0.023*	P=0.329	P=0.435
HISTCONT SAME RTE	P=0.657	P=0.090	P=1.000	P=1.000
HISTCONT ALL RTEs	P=0.411	P=0.008**	P=0.444	P=1.000
CURR VS HC SAME RTE	P=0.484			
CURR VS HC ALL RTEs	P=0.908			

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Harderian Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	6/50 (12%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	3/44.94	6/46.12	2/45.68	3/38.20
POLY-3 PERCENT (g)	6.7%	13%	4.4%	7.9%
TERMINAL (d)	2/35 (6%)	5/39 (13%)	2/37 (5%)	2/25 (8%)
FIRST INCIDENCE	667	574	729 (T)	718
HC TUMORS SAME ROUTE	30/250 (12%)			
HC TUMORS ALL ROUTES	65/550 (12%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.471N	P=0.255	P=0.492N	P=0.585
POLY 1.5	P=0.453N	P=0.249	P=0.497N	P=0.607
POLY 6	P=0.482N	P=0.263	P=0.486N	P=0.570
COCH-ARM / FISHERS	P=0.396N	P=0.243	P=0.500N	P=0.661N
MAX-ISO-POLY-3	P=0.446N	P=0.159	P=0.319N	P=0.423
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.205			
CURR VS HC ALL RTES	P=0.179			

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Harderian Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	7/50 (14%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	3/44.94	7/46.18	2/45.68	4/38.49
POLY-3 PERCENT (g)	6.7%	15.2%	4.4%	10.4%
TERMINAL (d)	2/35 (6%)	5/39 (13%)	2/37 (5%)	2/25 (8%)
FIRST INCIDENCE	667	574	729 (T)	650
HC TUMORS SAME ROUTE	40/250 (16%)			
HC TUMORS ALL ROUTES	82/550 (15%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.542	P=0.168	P=0.492N	P=0.416
POLY 1.5	P=0.564	P=0.164	P=0.497N	P=0.438
POLY 6	P=0.531	P=0.176	P=0.486N	P=0.403
COCH-ARM / FISHERS	P=0.508N	P=0.159	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.467N	P=0.100	P=0.319N	P=0.288
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.065			
CURR VS HC ALL RTES	P=0.060			

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Islets, Pancreatic Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/48 (0%)	0/48 (0%)	2/49 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.71	0/44.83	2/45.16	0/38.16
POLY-3 PERCENT (g)	0%	0%	4.4%	0%
TERMINAL (d)	0/35 (0%)	0/39 (0%)	1/37 (3%)	0/25 (0%)
FIRST INCIDENCE	---	---	597	---
HC TUMORS SAME ROUTE	4/248 (2%)			
HC TUMORS ALL ROUTES	8/548 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.497	(e)	P=0.244	(e)
POLY 1.5	P=0.531	(e)	P=0.243	(e)
POLY 6	P=0.469	(e)	P=0.248	(e)
COCH-ARM / FISHERS	P=0.608	(e)	P=0.253	(e)
MAX-ISO-POLY-3	P=0.291	(e)	P=0.082	(e)
HISTCONT SAME RTE	P=0.625	(e)	P=0.259	(e)
HISTCONT ALL RTES	P=0.589	(e)	P=0.137	(e)
CURR VS HC SAME RTE	P=0.386			
CURR VS HC ALL RTES	P=0.327			



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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Liver</b>				
<b>Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	17/50 (34%)	16/50 (32%)	15/50 (30%)	4/50 (8%)
POLY-3 RATE (b)	17/45.51	16/46.08	15/46.27	4/38.16
POLY-3 PERCENT (g)	37.4%	34.7%	32.4%	10.5%
TERMINAL (d)	15/35 (43%)	14/39 (36%)	13/37 (35%)	4/25 (16%)
FIRST INCIDENCE	590	611	554	729 (T)
HC TUMORS SAME ROUTE	142/250 (57%)			
HC TUMORS ALL ROUTES	328/550 (60%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.005N**	P=0.482N	P=0.391N	P=0.004N**
POLY 1.5	P=0.003N**	P=0.492N	P=0.404N	P=0.003N**
POLY 6	P=0.007N**	P=0.465N	P=0.370N	P=0.005N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500N	P=0.415N	P<0.001N**
MAX-ISO-POLY-3	P=0.007N**	P=0.395N	P=0.311N	P=0.003N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.011*			
CURR VS HC ALL RTES	P<0.001**			

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DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Liver</b>				
<b>Hepatocellular Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	17/50 (34%)	11/50 (22%)	13/50 (26%)	6/50 (12%)
POLY-3 RATE (b)	17/47.29	11/48.63	13/47.12	6/38.16
POLY-3 PERCENT (g)	36%	22.6%	27.6%	15.7%
TERMINAL (d)	8/35 (23%)	5/39 (13%)	8/37 (22%)	6/25 (24%)
FIRST INCIDENCE	519	396	527	729 (T)
HC TUMORS SAME ROUTE	98/250 (39%)			
HC TUMORS ALL ROUTES	188/550 (34%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.043N*	P=0.112N	P=0.258N	P=0.031N*
POLY 1.5	P=0.029N*	P=0.119N	P=0.259N	P=0.020N*
POLY 6	P=0.060N	P=0.108N	P=0.258N	P=0.046N*
COCH-ARM / FISHERS	P=0.011N*	P=0.133N	P=0.257N	P=0.008N**
MAX-ISO-POLY-3	P=0.047N*	P=0.077N	P=0.192N	P=0.027N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.622			
CURR VS HC ALL RTES	P=0.898			

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Liver</b>				
<b>Hepatocellular Carcinoma or Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	18/50 (36%)	11/50 (22%)	14/50 (28%)	6/50 (12%)
POLY-3 RATE (b)	18/47.85	11/48.63	14/47.12	6/38.16
POLY-3 PERCENT (g)	37.6%	22.6%	29.7%	15.7%
TERMINAL (d)	8/35 (23%)	5/39 (13%)	9/37 (24%)	6/25 (24%)
FIRST INCIDENCE	519	396	527	729 (T)
HC TUMORS SAME ROUTE	102/250 (41%)			
HC TUMORS ALL ROUTES	203/550 (37%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.035N*	P=0.082N	P=0.275N	P=0.021N*
POLY 1.5	P=0.022N*	P=0.085N	P=0.270N	P=0.013N*
POLY 6	P=0.052N	P=0.081N	P=0.283N	P=0.034N*
COCH-ARM / FISHERS	P=0.008N**	P=0.093N	P=0.260N	P=0.005N**
MAX-ISO-POLY-3	P=0.035N*	P=0.054N	P=0.210N	P=0.020N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.632			
CURR VS HC ALL RTES	P=0.778			

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DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Liver</b>				
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	31/50 (62%)	27/50 (54%)	25/50 (50%)	8/50 (16%)
POLY-3 RATE (b)	31/47.76	27/49.10	25/47.71	8/38.16
POLY-3 PERCENT (g)	64.9%	55%	52.4%	21%
TERMINAL (d)	21/35 (60%)	19/39 (49%)	18/37 (49%)	8/25 (32%)
FIRST INCIDENCE	519	396	527	729 (T)
HC TUMORS SAME ROUTE	187/250 (75%)			
HC TUMORS ALL ROUTES	413/550 (75%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001N**	P=0.214N	P=0.148N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.233N	P=0.152N	P<0.001N**
POLY 6	P<0.001N**	P=0.201N	P=0.146N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.272N	P=0.157N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.162N	P=0.104N	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.161			
CURR VS HC ALL RTES	P=0.037*			

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Liver</b>				
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	32/50 (64%)	27/50 (54%)	26/50 (52%)	8/50 (16%)
POLY-3 RATE (b)	32/48.32	27/49.10	26/47.71	8/38.16
POLY-3 PERCENT (g)	66.2%	55%	54.5%	21%
TERMINAL (d)	21/35 (60%)	19/39 (49%)	19/37 (51%)	8/25 (32%)
FIRST INCIDENCE	519	396	527	729 (T)
HC TUMORS SAME ROUTE	189/250 (76%)			
HC TUMORS ALL ROUTES	416/550 (76%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001N**	P=0.175N	P=0.165N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.185N	P=0.161N	P<0.001N**
POLY 6	P<0.001N**	P=0.172N	P=0.172N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.208N	P=0.156N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.129N	P=0.119N	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.184			
CURR VS HC ALL RTES	P=0.044*			

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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Lung</b>				
<b>Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	5/50 (10%)	5/49 (10%)	5/50 (10%)	4/50 (8%)
POLY-3 RATE (b)	5/44.70	5/45.12	5/45.71	4/38.63
POLY-3 PERCENT (g)	11.2%	11.1%	10.9%	10.4%
TERMINAL (d)	5/35 (14%)	5/39 (13%)	4/37 (11%)	2/25 (8%)
FIRST INCIDENCE	729 (T)	729 (T)	722	650
HC TUMORS SAME ROUTE	35/250 (14%)			
HC TUMORS ALL ROUTES	83/550 (15%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.511N	P=0.625N	P=0.616N	P=0.591N
POLY 1.5	P=0.488N	P=0.627	P=0.624N	P=0.568N
POLY 6	P=0.521N	P=0.611N	P=0.604N	P=0.601N
COCH-ARM / FISHERS	P=0.415N	P=0.617	P=0.630N	P=0.500N
MAX-ISO-POLY-3	P=0.697N	P=0.493N	P=0.484N	P=0.454N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.477			
CURR VS HC ALL RTES	P=0.310			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Lung</b>				
<b>Alveolar/Bronchiolar Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	5/50 (10%)	3/49 (6%)	6/50 (12%)	3/50 (6%)
POLY-3 RATE (b)	5/44.73	3/45.12	6/46.23	3/38.16
POLY-3 PERCENT (g)	11.2%	6.7%	13%	7.9%
TERMINAL (d)	4/35 (11%)	3/39 (8%)	3/37 (8%)	3/25 (12%)
FIRST INCIDENCE	722	729 (T)	588	729 (T)
HC TUMORS SAME ROUTE	42/250 (17%)			
HC TUMORS ALL ROUTES	75/550 (14%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.481N	P=0.351N	P=0.523	P=0.446N
POLY 1.5	P=0.453N	P=0.359N	P=0.511	P=0.422N
POLY 6	P=0.500N	P=0.340N	P=0.542	P=0.463N
COCH-ARM / FISHERS	P=0.375N	P=0.369N	P=0.500	P=0.357N
MAX-ISO-POLY-3	P=0.517N	P=0.229N	P=0.396	P=0.320N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.260			
CURR VS HC ALL RTES	P=0.453			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Lung</b>				
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	9/50 (18%)	8/49 (16%)	10/50 (20%)	7/50 (14%)
POLY-3 RATE (b)	9/44.73	8/45.12	10/46.23	7/38.63
POLY-3 PERCENT (g)	20.1%	17.7%	21.6%	18.1%
TERMINAL (d)	8/35 (23%)	8/39 (21%)	7/37 (19%)	5/25 (20%)
FIRST INCIDENCE	722	729 (T)	588	650
HC TUMORS SAME ROUTE	69/250 (28%)			
HC TUMORS ALL ROUTES	147/550 (27%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.508N	P=0.492N	P=0.532	P=0.519N
POLY 1.5	P=0.474N	P=0.505N	P=0.515	P=0.487N
POLY 6	P=0.525N	P=0.473N	P=0.558	P=0.534N
COCH-ARM / FISHERS	P=0.368N	P=0.518N	P=0.500	P=0.393N
MAX-ISO-POLY-3	P=0.646N	P=0.386N	P=0.429	P=0.413N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.162			
CURR VS HC ALL RTES	P=0.161			



Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
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 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Nose Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/49 (0%)	0/48 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.07	0/44.83	0/45.68	0/38.16
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/39 (0%)	0/37 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	0/249 (0%)			
HC TUMORS ALL ROUTES	0/549 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Pituitary Gland: Pars Distalis or Unspecified Site Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.70	0/45.12	0/45.68	0/38.16
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/39 (0%)	0/37 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	1/245 (0%)			
HC TUMORS ALL ROUTES	2/540 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.70	0/45.12	0/45.68	0/38.16
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/39 (0%)	0/37 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	1/245 (0%)			
HC TUMORS ALL ROUTES	2/540 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
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 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Spleen</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/48 (0%)	2/49 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.71	2/45.53	0/45.68	0/38.16
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/35 (0%)	1/39 (3%)	0/37 (0%)	0/25 (0%)
FIRST INCIDENCE	---	6/11	---	---
HC TUMORS SAME ROUTE	7/248 (3%)			
HC TUMORS ALL ROUTES	14/548 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.430N	P=0.246	(e)	(e)
POLY 1.5	P=0.425N	P=0.244	(e)	(e)
POLY 6	P=0.431N	P=0.250	(e)	(e)
COCH-ARM / FISHERS	P=0.408N	P=0.253	(e)	(e)
MAX-ISO-POLY-3	P=0.315N	P=0.084	(e)	(e)
HISTCONT SAME RTE	P=1.000	P=1.000	(e)	(e)
HISTCONT ALL RTES	P=1.000	P=0.433	(e)	(e)
CURR VS HC SAME RTE	P=0.256			
CURR VS HC ALL RTES	P=0.205			

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 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.70	2/46.02	0/45.68	1/38.34
POLY-3 PERCENT (g)	2.2%	4.4%	0%	2.6%
TERMINAL (d)	1/35 (3%)	1/39 (3%)	0/37 (0%)	0/25 (0%)
FIRST INCIDENCE	729 (T)	611	---	680
HC TUMORS SAME ROUTE	12/250 (5%)			
HC TUMORS ALL ROUTES	37/550 (7%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.521N	P=0.510	P=0.496N	P=0.725
POLY 1.5	P=0.519N	P=0.505	P=0.498N	P=0.735
POLY 6	P=0.519N	P=0.518	P=0.492N	P=0.720
COCH-ARM / FISHERS	P=0.505N	P=0.500	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.452N	P=0.292	P=0.158N	P=0.459
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.458			
CURR VS HC ALL RTES	P=0.199			

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P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Hemangiosarcoma or Hemangioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/44.70	2/46.02	0/45.68	2/38.34
POLY-3 PERCENT (g)	2.2%	4.4%	0%	5.2%
TERMINAL (d)	1/35 (3%)	1/39 (3%)	0/37 (0%)	1/25 (4%)
FIRST INCIDENCE	729 (T)	611	---	680
HC TUMORS SAME ROUTE	14/250 (6%)			
HC TUMORS ALL ROUTES	43/550 (8%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.427	P=0.510	P=0.496N	P=0.447
POLY 1.5	P=0.435	P=0.505	P=0.498N	P=0.461
POLY 6	P=0.423	P=0.518	P=0.492N	P=0.439
COCH-ARM / FISHERS	P=0.466	P=0.500	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.371	P=0.292	P=0.158N	P=0.253
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.354			
CURR VS HC ALL RTES	P=0.130			

Experiment Number: 20725 - 04  
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 Species/Strain: MICE/B6C3F1

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Histiocytic Sarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.70	1/45.67	2/46.12	0/38.16
POLY-3 PERCENT (g)	0%	2.2%	4.3%	0%
TERMINAL (d)	0/35 (0%)	0/39 (0%)	1/37 (3%)	0/25 (0%)
FIRST INCIDENCE	---	713	600	---
HC TUMORS SAME ROUTE	5/250 (2%)			
HC TUMORS ALL ROUTES	9/550 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.595	P=0.504	P=0.244	(e)
POLY 1.5	P=0.622	P=0.502	P=0.241	(e)
POLY 6	P=0.575	P=0.508	P=0.250	(e)
COCH-ARM / FISHERS	P=0.618N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.369	P=0.164	P=0.083	(e)
HISTCONT SAME RTE	P=0.741	P=1.000	P=0.281	(e)
HISTCONT ALL RTES	P=0.671	P=1.000	P=0.175	(e)
CURR VS HC SAME RTE	P=0.286			
CURR VS HC ALL RTES	P=0.307			

Experiment Number: 20725 - 04  
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 Species/Strain: MICE/B6C3F1

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	6/50 (12%)	4/50 (8%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	6/45.57	4/46.60	3/46.15	2/38.20
POLY-3 PERCENT (g)	13.2%	8.6%	6.5%	5.2%
TERMINAL (d)	4/35 (11%)	2/39 (5%)	0/37 (0%)	1/25 (4%)
FIRST INCIDENCE	519	480	637	718
HC TUMORS SAME ROUTE	19/250 (8%)			
HC TUMORS ALL ROUTES	35/550 (6%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.133N	P=0.356N	P=0.236N	P=0.197N
POLY 1.5	P=0.122N	P=0.362N	P=0.240N	P=0.178N
POLY 6	P=0.140N	P=0.345N	P=0.227N	P=0.213N
COCH-ARM / FISHERS	P=0.094N	P=0.370N	P=0.243N	P=0.134N
MAX-ISO-POLY-3	P=0.199N	P=0.244N	P=0.143N	P=0.130N
HISTCONT SAME RTE	P=1.000	P=1.000	P=1.000	P=1.000
HISTCONT ALL RTES	P=1.000	P=0.481	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.289			
CURR VS HC ALL RTES	P=0.150			



Experiment Number: 20725 - 04  
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 2,3-Butanedione  
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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	22/50 (44%)	27/50 (54%)	21/50 (42%)	11/50 (22%)
POLY-3 RATE (b)	22/45.75	27/46.59	21/46.72	11/38.68
POLY-3 PERCENT (g)	48.1%	58%	45%	28.4%
TERMINAL (d)	19/35 (54%)	24/39 (62%)	18/37 (49%)	8/25 (32%)
FIRST INCIDENCE	590	574	554	650
HC TUMORS SAME ROUTE	186/250 (74%)			
HC TUMORS ALL ROUTES	411/550 (75%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.019N*	P=0.226	P=0.462N	P=0.049N*
POLY 1.5	P=0.013N*	P=0.217	P=0.482N	P=0.036N*
POLY 6	P=0.025N*	P=0.241	P=0.433N	P=0.059N
COCH-ARM / FISHERS	P=0.004N**	P=0.212	P=0.500N	P=0.016N*
MAX-ISO-POLY-3	P=0.028N*	P=0.170	P=0.380N	P=0.040N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P<0.001**			
CURR VS HC ALL RTES	P<0.001**			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	27/50 (54%)	20/50 (40%)	24/50 (48%)	12/50 (24%)
POLY-3 RATE (b)	27/48.99	20/49.38	24/48.07	12/38.68
POLY-3 PERCENT (g)	55.1%	40.5%	49.9%	31%
TERMINAL (d)	14/35 (40%)	11/39 (28%)	14/37 (38%)	9/25 (36%)
FIRST INCIDENCE	519	396	527	650
HC TUMORS SAME ROUTE	156/250 (62%)			
HC TUMORS ALL ROUTES	324/550 (59%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.038N*	P=0.105N	P=0.379N	P=0.019N*
POLY 1.5	P=0.018N*	P=0.107N	P=0.369N	P=0.009N**
POLY 6	P=0.068N	P=0.105N	P=0.388N	P=0.038N*
COCH-ARM / FISHERS	P=0.003N**	P=0.115N	P=0.345N	P=0.002N**
MAX-ISO-POLY-3	P=0.036N*	P=0.073N	P=0.306N	P=0.019N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.329			
CURR VS HC ALL RTES	P=0.389			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Malignant and Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	37/50 (74%)	37/50 (74%)	36/50 (72%)	18/50 (36%)
POLY-3 RATE (b)	37/48.99	37/49.38	36/49.09	18/38.72
POLY-3 PERCENT (g)	75.5%	74.9%	73.3%	46.5%
TERMINAL (d)	24/35 (69%)	28/39 (72%)	24/37 (65%)	14/25 (56%)
FIRST INCIDENCE	519	396	527	650
HC TUMORS SAME ROUTE	227/250 (91%)			
HC TUMORS ALL ROUTES	503/550 (92%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.003N**	P=0.565N	P=0.493N	P=0.003N**
POLY 1.5	P<0.001N**	P=0.570N	P=0.504N	P<0.001N**
POLY 6	P=0.010N**	P=0.569N	P=0.474N	P=0.011N*
COCH-ARM / FISHERS	P<0.001N**	P=0.590N	P=0.500N	P<0.001N**
MAX-ISO-POLY-3	P=0.004N**	P=0.471N	P=0.400N	P=0.004N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.003**			
CURR VS HC ALL RTES	P<0.001**			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
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 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Adrenal Cortex</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.98	0/47.59	0/47.33	0/31.98
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	1/36 (3%)	0/40 (0%)	0/42 (0%)	0/17 (0%)
FIRST INCIDENCE	731 (T)	---	---	---
HC TUMORS SAME ROUTE	2/249 (1%)			
HC TUMORS ALL ROUTES	4/546 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Harderian Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	3/44.98	3/47.59	3/47.33	2/33.05
POLY-3 PERCENT (g)	6.7%	6.3%	6.3%	6.1%
TERMINAL (d)	3/36 (8%)	3/40 (8%)	3/42 (7%)	0/17 (0%)
FIRST INCIDENCE	731 (T)	731 (T)	731 (T)	547
HC TUMORS SAME ROUTE	10/250 (4%)			
HC TUMORS ALL ROUTES	36/550 (7%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.526N	P=0.636N	P=0.638N	P=0.636N
POLY 1.5	P=0.492N	P=0.644N	P=0.646N	P=0.594N
POLY 6	P=0.548N	P=0.626N	P=0.628N	P=0.668N
COCH-ARM / FISHERS	P=0.397N	P=0.661N	P=0.661N	P=0.500N
MAX-ISO-POLY-3	P=0.707N	P=0.471N	P=0.474N	P=0.462N
HISTCONT SAME RTE	P=0.286	P=0.383	P=0.378	P=1.000
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.540			
CURR VS HC ALL RTES	P=0.859			

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 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Harderian Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	4/50 (8%)	3/50 (6%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	4/45.14	3/47.59	3/47.33	2/33.05
POLY-3 PERCENT (g)	8.9%	6.3%	6.3%	6.1%
TERMINAL (d)	3/36 (8%)	3/40 (8%)	3/42 (7%)	0/17 (0%)
FIRST INCIDENCE	690	731 (T)	731 (T)	547
HC TUMORS SAME ROUTE	20/250 (8%)			
HC TUMORS ALL ROUTES	51/550 (9%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.387N	P=0.471N	P=0.474N	P=0.488N
POLY 1.5	P=0.356N	P=0.480N	P=0.482N	P=0.439N
POLY 6	P=0.407N	P=0.461N	P=0.464N	P=0.529N
COCH-ARM / FISHERS	P=0.272N	P=0.500N	P=0.500N	P=0.339N
MAX-ISO-POLY-3	P=0.550N	P=0.326N	P=0.328N	P=0.346N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.974			
CURR VS HC ALL RTEs	P=0.737			

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P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Islets, Pancreatic Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/49 (0%)	0/48 (0%)
POLY-3 RATE (b)	0/44.23	0/47.59	0/46.80	0/31.77
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/36 (0%)	0/40 (0%)	0/42 (0%)	0/17 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	2/250 (1%)			
HC TUMORS ALL ROUTES	4/549 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTEs	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTEs	(n)			

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 Test Type: CHRONIC  
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 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Liver</b>				
<b>Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	6/50 (12%)	11/50 (22%)	7/50 (14%)	3/50 (6%)
POLY-3 RATE (b)	6/45.26	11/47.59	7/47.33	3/32.47
POLY-3 PERCENT (g)	13.3%	23.1%	14.8%	9.2%
TERMINAL (d)	5/36 (14%)	11/40 (28%)	7/42 (17%)	2/17 (12%)
FIRST INCIDENCE	653	731 (T)	731 (T)	585
HC TUMORS SAME ROUTE	78/250 (31%)			
HC TUMORS ALL ROUTES	165/549 (30%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.281N	P=0.168	P=0.534	P=0.428N
POLY 1.5	P=0.215N	P=0.161	P=0.524	P=0.363N
POLY 6	P=0.335N	P=0.177	P=0.548	P=0.487N
COCH-ARM / FISHERS	P=0.101N	P=0.143	P=0.500	P=0.243N
MAX-ISO-POLY-3	P=0.307N	P=0.115	P=0.416	P=0.322N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.018*			
CURR VS HC ALL RTES	P=0.014*			



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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Liver</b>				
<b>Hepatocellular Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	5/50 (10%)	5/50 (10%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	5/44.98	5/47.59	3/47.33	0/31.98
POLY-3 PERCENT (g)	11.1%	10.5%	6.3%	0%
TERMINAL (d)	5/36 (14%)	5/40 (13%)	3/42 (7%)	0/17 (0%)
FIRST INCIDENCE	731 (T)	731 (T)	731 (T)	---
HC TUMORS SAME ROUTE	41/250 (16%)			
HC TUMORS ALL ROUTES	76/549 (14%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.047N*	P=0.594N	P=0.329N	P=0.073N
POLY 1.5	P=0.037N*	P=0.605N	P=0.338N	P=0.055N
POLY 6	P=0.057N	P=0.580N	P=0.317N	P=0.092N
COCH-ARM / FISHERS	P=0.019N*	P=0.630N	P=0.357N	P=0.028N*
MAX-ISO-POLY-3	P=0.074N	P=0.463N	P=0.215N	P=0.048N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.214			
CURR VS HC ALL RTES	P=0.429			

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Liver</b>				
<b>Hepatocellular Carcinoma or Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	6/50 (12%)	5/50 (10%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	6/45.45	5/47.59	3/47.33	0/31.98
POLY-3 PERCENT (g)	13.2%	10.5%	6.3%	0%
TERMINAL (d)	5/36 (14%)	5/40 (13%)	3/42 (7%)	0/17 (0%)
FIRST INCIDENCE	590	731 (T)	731 (T)	---
HC TUMORS SAME ROUTE	41/250 (16%)			
HC TUMORS ALL ROUTES	77/549 (14%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.026N*	P=0.468N	P=0.222N	P=0.046N*
POLY 1.5	P=0.020N*	P=0.477N	P=0.228N	P=0.032N*
POLY 6	P=0.033N*	P=0.457N	P=0.214N	P=0.062N
COCH-ARM / FISHERS	P=0.010N**	P=0.500N	P=0.243N	P=0.013N*
MAX-ISO-POLY-3	P=0.040N*	P=0.347N	P=0.137N	P=0.034N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.380			
CURR VS HC ALL RTES	P=0.645			

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Liver</b>				
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	11/50 (22%)	15/50 (30%)	9/50 (18%)	3/50 (6%)
POLY-3 RATE (b)	11/45.26	15/47.59	9/47.33	3/32.47
POLY-3 PERCENT (g)	24.3%	31.5%	19%	9.2%
TERMINAL (d)	10/36 (28%)	15/40 (38%)	9/42 (21%)	2/17 (12%)
FIRST INCIDENCE	653	731 (T)	731 (T)	585
HC TUMORS SAME ROUTE	102/250 (41%)			
HC TUMORS ALL ROUTES	207/549 (38%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.044N*	P=0.293	P=0.358N	P=0.083N
POLY 1.5	P=0.026N*	P=0.280	P=0.371N	P=0.054N
POLY 6	P=0.062N	P=0.309	P=0.341N	P=0.117N
COCH-ARM / FISHERS	P=0.007N**	P=0.247	P=0.402N	P=0.020N*
MAX-ISO-POLY-3	P=0.068N	P=0.225	P=0.273N	P=0.071N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.024*			
CURR VS HC ALL RTEs	P=0.038*			

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Liver</b>				
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	12/50 (24%)	15/50 (30%)	9/50 (18%)	3/50 (6%)
POLY-3 RATE (b)	12/45.74	15/47.59	9/47.33	3/32.47
POLY-3 PERCENT (g)	26.2%	31.5%	19%	9.2%
TERMINAL (d)	10/36 (28%)	15/40 (38%)	9/42 (21%)	2/17 (12%)
FIRST INCIDENCE	590	731 (T)	731 (T)	585
HC TUMORS SAME ROUTE	102/250 (41%)			
HC TUMORS ALL ROUTES	207/549 (38%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.030N*	P=0.369	P=0.279N	P=0.058N
POLY 1.5	P=0.017N*	P=0.358	P=0.288N	P=0.035N*
POLY 6	P=0.045N*	P=0.380	P=0.268N	P=0.088N
COCH-ARM / FISHERS	P=0.004N**	P=0.326	P=0.312N	P=0.011N*
MAX-ISO-POLY-3	P=0.045N*	P=0.291	P=0.207N	P=0.053N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.039*			
CURR VS HC ALL RTES	P=0.061			

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 Test Type: CHRONIC  
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 Species/Strain: MICE/B6C3F1

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 2,3-Butanedione  
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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Lung</b>				
<b>Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	3/50 (6%)	5/50 (10%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/44.98	5/47.59	2/47.40	1/31.98
POLY-3 PERCENT (g)	6.7%	10.5%	4.2%	3.1%
TERMINAL (d)	3/36 (8%)	5/40 (13%)	1/42 (2%)	1/17 (6%)
FIRST INCIDENCE	731 (T)	731 (T)	714	731 (T)
HC TUMORS SAME ROUTE	12/249 (5%)			
HC TUMORS ALL ROUTES	27/549 (5%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.229N	P=0.388	P=0.476N	P=0.435N
POLY 1.5	P=0.201N	P=0.378	P=0.484N	P=0.391N
POLY 6	P=0.249N	P=0.400	P=0.465N	P=0.475N
COCH-ARM / FISHERS	P=0.139N	P=0.357	P=0.500N	P=0.309N
MAX-ISO-POLY-3	P=0.354N	P=0.263	P=0.307N	P=0.282N
HISTCONT SAME RTE	P=0.690	P=0.087	P=1.000	P=1.000
HISTCONT ALL RTES	P=0.720	P=0.093	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.731			
CURR VS HC ALL RTES	P=0.763			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Lung</b>				
<b>Alveolar/Bronchiolar Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	3/45.23	1/47.72	2/47.67	0/31.98
POLY-3 PERCENT (g)	6.6%	2.1%	4.2%	0%
TERMINAL (d)	2/36 (6%)	0/40 (0%)	1/42 (2%)	0/17 (0%)
FIRST INCIDENCE	663	697	639	---
HC TUMORS SAME ROUTE	17/249 (7%)			
HC TUMORS ALL ROUTES	24/549 (4%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.154N	P=0.286N	P=0.476N	P=0.194N
POLY 1.5	P=0.138N	P=0.292N	P=0.484N	P=0.166N
POLY 6	P=0.168N	P=0.279N	P=0.466N	P=0.222N
COCH-ARM / FISHERS	P=0.102N	P=0.309N	P=0.500N	P=0.121N
MAX-ISO-POLY-3	P=0.169N	P=0.147N	P=0.307N	P=0.105N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.814			
CURR VS HC ALL RTES	P=0.629			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Lung</b>				
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	6/50 (12%)	6/50 (12%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	6/45.23	6/47.72	4/47.73	1/31.98
POLY-3 PERCENT (g)	13.3%	12.6%	8.4%	3.1%
TERMINAL (d)	5/36 (14%)	5/40 (13%)	2/42 (5%)	1/17 (6%)
FIRST INCIDENCE	663	697	639	731 (T)
HC TUMORS SAME ROUTE	28/249 (11%)			
HC TUMORS ALL ROUTES	50/549 (9%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.087N	P=0.582N	P=0.336N	P=0.136N
POLY 1.5	P=0.067N	P=0.594N	P=0.347N	P=0.103N
POLY 6	P=0.104N	P=0.569N	P=0.321N	P=0.171N
COCH-ARM / FISHERS	P=0.033N*	P=0.620N	P=0.370N	P=0.056N
MAX-ISO-POLY-3	P=0.136N	P=0.461N	P=0.231N	P=0.098N
HISTCONT SAME RTE	P=1.000	P=1.000	P=1.000	P=1.000
HISTCONT ALL RTES	P=1.000	P=0.382	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.904			
CURR VS HC ALL RTES	P=0.535			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Nose Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.98	0/47.59	0/47.33	2/32.07
POLY-3 PERCENT (g)	0%	0%	0%	6.2%
TERMINAL (d)	0/36 (0%)	0/40 (0%)	0/42 (0%)	1/17 (6%)
FIRST INCIDENCE	---	---	---	708
HC TUMORS SAME ROUTE	0/250 (0%)			
HC TUMORS ALL ROUTES	0/548 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.038*	(e)	(e)	P=0.171
POLY 1.5	P=0.039*	(e)	(e)	P=0.191
POLY 6	P=0.038*	(e)	(e)	P=0.156
COCH-ARM / FISHERS	P=0.047*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.032*	(e)	(e)	P=0.074
HISTCONT SAME RTE	P=0.032*	(e)	(e)	P=0.032*
HISTCONT ALL RTES	P=0.004**	(e)	(e)	P=0.002**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=1.000			



Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Ovary</b>				
<b>Cystadenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/49 (0%)	2/50 (4%)	3/49 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/43.98	2/47.59	3/46.33	0/31.98
POLY-3 PERCENT (g)	0%	4.2%	6.5%	0%
TERMINAL (d)	0/35 (0%)	2/40 (5%)	3/41 (7%)	0/17 (0%)
FIRST INCIDENCE	---	731 (T)	731 (T)	---
HC TUMORS SAME ROUTE	6/248 (2%)			
HC TUMORS ALL ROUTES	17/546 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.465	P=0.255	P=0.128	(e)
POLY 1.5	P=0.550	P=0.251	P=0.125	(e)
POLY 6	P=0.392	P=0.260	P=0.133	(e)
COCH-ARM / FISHERS	P=0.530N	P=0.253	P=0.121	(e)
MAX-ISO-POLY-3	P=0.336	P=0.092	P=0.046*	(e)
HISTCONT SAME RTE	P=0.558	P=0.408	P=0.047*	(e)
HISTCONT ALL RTES	P=0.706	P=1.000	P=0.084	(e)
CURR VS HC SAME RTE	P=0.197			
CURR VS HC ALL RTES	P=0.163			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Ovary</b>				
<b>Luteoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/49 (0%)	1/50 (2%)	3/49 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/43.98	1/47.59	3/46.33	0/31.98
POLY-3 PERCENT (g)	0%	2.1%	6.5%	0%
TERMINAL (d)	0/35 (0%)	1/40 (3%)	3/41 (7%)	0/17 (0%)
FIRST INCIDENCE	---	731 (T)	731 (T)	---
HC TUMORS SAME ROUTE	2/248 (1%)			
HC TUMORS ALL ROUTES	2/546 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.390	P=0.516	P=0.128	(e)
POLY 1.5	P=0.474	P=0.512	P=0.125	(e)
POLY 6	P=0.318	P=0.520	P=0.133	(e)
COCH-ARM / FISHERS	P=0.630N	P=0.505	P=0.121	(e)
MAX-ISO-POLY-3	P=0.307	P=0.177	P=0.046*	(e)
HISTCONT SAME RTE	P=0.273	P=1.000	P=0.020*	(e)
HISTCONT ALL RTES	P=0.040*	P=0.232	P<0.001**	(e)
CURR VS HC SAME RTE	P=0.452			
CURR VS HC ALL RTES	P=0.444			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Pituitary Gland: Pars Distalis or Unspecified Site Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/49 (4%)	4/49 (8%)	2/50 (4%)	0/48 (0%)
POLY-3 RATE (b)	2/44.23	4/47.51	2/47.33	0/31.07
POLY-3 PERCENT (g)	4.5%	8.4%	4.2%	0%
TERMINAL (d)	1/35 (3%)	2/39 (5%)	2/42 (5%)	0/17 (0%)
FIRST INCIDENCE	663	561	731 (T)	---
HC TUMORS SAME ROUTE	33/244 (14%)			
HC TUMORS ALL ROUTES	48/542 (9%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.199N	P=0.371	P=0.669N	P=0.323N
POLY 1.5	P=0.171N	P=0.360	P=0.674N	P=0.294N
POLY 6	P=0.225N	P=0.384	P=0.662N	P=0.351N
COCH-ARM / FISHERS	P=0.117N	P=0.339	P=0.684N	P=0.253N
MAX-ISO-POLY-3	P=0.236N	P=0.235	P=0.472N	P=0.156N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.056			
CURR VS HC ALL RTES	P=0.249			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/49 (4%)	5/49 (10%)	3/50 (6%)	0/48 (0%)
POLY-3 RATE (b)	2/44.23	5/47.51	3/47.33	0/31.07
POLY-3 PERCENT (g)	4.5%	10.5%	6.3%	0%
TERMINAL (d)	1/35 (3%)	3/39 (8%)	3/42 (7%)	0/17 (0%)
FIRST INCIDENCE	663	561	731 (T)	---
HC TUMORS SAME ROUTE	36/244 (15%)			
HC TUMORS ALL ROUTES	51/542 (9%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.235N	P=0.246	P=0.531	P=0.323N
POLY 1.5	P=0.193N	P=0.236	P=0.524	P=0.294N
POLY 6	P=0.274N	P=0.259	P=0.539	P=0.351N
COCH-ARM / FISHERS	P=0.120N	P=0.218	P=0.510	P=0.253N
MAX-ISO-POLY-3	P=0.216N	P=0.148	P=0.355	P=0.156N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.048*			
CURR VS HC ALL RTES	P=0.218			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
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 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Spleen Hemangiosarcoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/48 (0%)
POLY-3 RATE (b)	0/44.98	1/47.59	2/47.41	0/31.77
POLY-3 PERCENT (g)	0%	2.1%	4.2%	0%
TERMINAL (d)	0/36 (0%)	1/40 (3%)	1/42 (2%)	0/17 (0%)
FIRST INCIDENCE	---	731 (T)	713	---
HC TUMORS SAME ROUTE	6/249 (2%)			
HC TUMORS ALL ROUTES	8/548 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.490	P=0.511	P=0.249	(e)
POLY 1.5	P=0.558	P=0.508	P=0.245	(e)
POLY 6	P=0.426	P=0.516	P=0.255	(e)
COCH-ARM / FISHERS	P=0.629N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.405	P=0.173	P=0.087	(e)
HISTCONT SAME RTE	P=1.000	P=1.000	P=0.457	(e)
HISTCONT ALL RTEs	P=0.647	P=1.000	P=0.202	(e)
CURR VS HC SAME RTE	P=0.273			
CURR VS HC ALL RTEs	P=0.381			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

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 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>Uterus</b>				
<b>Polyp Stromal</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.98	2/47.59	2/47.33	0/31.98
POLY-3 PERCENT (g)	0%	4.2%	4.2%	0%
TERMINAL (d)	0/36 (0%)	2/40 (5%)	2/42 (5%)	0/17 (0%)
FIRST INCIDENCE	---	731 (T)	731 (T)	---
HC TUMORS SAME ROUTE	9/250 (4%)			
HC TUMORS ALL ROUTES	16/550 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.552	P=0.250	P=0.249	(e)
POLY 1.5	P=0.605N	P=0.246	P=0.245	(e)
POLY 6	P=0.489	P=0.255	P=0.254	(e)
COCH-ARM / FISHERS	P=0.505N	P=0.247	P=0.247	(e)
MAX-ISO-POLY-3	P=0.381	P=0.088	P=0.087	(e)
HISTCONT SAME RTE	P=1.000	P=1.000	P=1.000	(e)
HISTCONT ALL RTES	P=1.000	P=1.000	P=1.000	(e)
CURR VS HC SAME RTE	P=0.166			
CURR VS HC ALL RTES	P=0.204			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/44.98	2/47.70	2/47.41	2/32.69
POLY-3 PERCENT (g)	0%	4.2%	4.2%	6.1%
TERMINAL (d)	0/36 (0%)	1/40 (3%)	1/42 (2%)	0/17 (0%)
FIRST INCIDENCE	---	703	713	605
HC TUMORS SAME ROUTE	16/250 (6%)			
HC TUMORS ALL ROUTES	27/550 (5%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.134	P=0.251	P=0.249	P=0.175
POLY 1.5	P=0.162	P=0.246	P=0.245	P=0.193
POLY 6	P=0.116	P=0.256	P=0.255	P=0.161
COCH-ARM / FISHERS	P=0.239	P=0.247	P=0.247	P=0.247
MAX-ISO-POLY-3	P=0.192	P=0.089	P=0.087	P=0.075
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	P=0.715	P=1.000	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.042*			
CURR VS HC ALL RTES	P=0.099			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Hemangiosarcoma or Hemangioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	0/44.98	2/47.70	3/47.41	3/33.27
POLY-3 PERCENT (g)	0%	4.2%	6.3%	9%
TERMINAL (d)	0/36 (0%)	1/40 (3%)	2/42 (5%)	0/17 (0%)
FIRST INCIDENCE	---	703	713	547
HC TUMORS SAME ROUTE	17/250 (7%)			
HC TUMORS ALL ROUTES	31/550 (6%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.049*	P=0.251	P=0.128	P=0.074
POLY 1.5	P=0.063	P=0.246	P=0.125	P=0.086
POLY 6	P=0.041*	P=0.256	P=0.133	P=0.066
COCH-ARM / FISHERS	P=0.110	P=0.247	P=0.121	P=0.121
MAX-ISO-POLY-3	P=0.076	P=0.089	P=0.046*	P=0.037*
HISTCONT SAME RTE	P=0.367	P=1.000	P=1.000	P=1.000
HISTCONT ALL RTES	P=0.450	P=1.000	P=1.000	P=0.378
CURR VS HC SAME RTE	P=0.035*			
CURR VS HC ALL RTES	P=0.070			



Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016  
 Time Report Requested: 10:33:42  
 First Dose M/F: 08/31/09 / 08/31/09  
 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Histiocytic Sarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.66	3/47.91	0/47.33	1/32.94
POLY-3 PERCENT (g)	2.2%	6.3%	0%	3%
TERMINAL (d)	0/36 (0%)	2/40 (5%)	0/42 (0%)	0/17 (0%)
FIRST INCIDENCE	499	644	---	252
HC TUMORS SAME ROUTE	12/250 (5%)			
HC TUMORS ALL ROUTES	18/550 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.458N	P=0.323	P=0.493N	P=0.682
POLY 1.5	P=0.450N	P=0.317	P=0.495N	P=0.710
POLY 6	P=0.457N	P=0.330	P=0.490N	P=0.656
COCH-ARM / FISHERS	P=0.417N	P=0.309	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.420N	P=0.173	P=0.159N	P=0.420
HISTCONT SAME RTE	P=1.000	P=1.000	P=1.000	P=1.000
HISTCONT ALL RTES	P=1.000	P=0.214	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.351			
CURR VS HC ALL RTES	P=0.599			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
 Route: RESPIRATORY EXPOSURE WHOLE BODY  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 2,3-Butanedione  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	9/50 (18%)	6/50 (12%)	16/50 (32%)	4/50 (8%)
POLY-3 RATE (b)	9/45.24	6/47.79	16/48.19	4/33.47
POLY-3 PERCENT (g)	19.9%	12.6%	33.2%	12%
TERMINAL (d)	7/36 (19%)	5/40 (13%)	14/42 (33%)	1/17 (6%)
FIRST INCIDENCE	687	680	592	325
HC TUMORS SAME ROUTE	63/250 (25%)			
HC TUMORS ALL ROUTES	109/550 (20%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.527	P=0.249N	P=0.110	P=0.268N
POLY 1.5	P=0.438N	P=0.261N	P=0.100	P=0.209N
POLY 6	P=0.424	P=0.235N	P=0.125	P=0.325N
COCH-ARM / FISHERS	P=0.211N	P=0.288N	P=0.083	P=0.117N
MAX-ISO-POLY-3	P=0.292N	P=0.175N	P=0.078	P=0.209N
HISTCONT SAME RTE	P=1.000	P=1.000	P=0.288	P=1.000
HISTCONT ALL RTES	P=0.663	P=1.000	P=0.063	P=1.000
CURR VS HC SAME RTE	P=0.285			
CURR VS HC ALL RTES	P=0.733			

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P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
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 Lab: BNW

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	15/50 (30%)	24/50 (48%)	22/50 (44%)	6/50 (12%)
POLY-3 RATE (b)	15/45.91	24/48.89	22/47.73	6/33.05
POLY-3 PERCENT (g)	32.7%	49.1%	46.1%	18.2%
TERMINAL (d)	11/36 (31%)	20/40 (50%)	20/42 (48%)	4/17 (24%)
FIRST INCIDENCE	653	561	639	547
HC TUMORS SAME ROUTE	135/250 (54%)			
HC TUMORS ALL ROUTES	279/550 (51%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.148N	P=0.076	P=0.130	P=0.121N
POLY 1.5	P=0.066N	P=0.067	P=0.124	P=0.074N
POLY 6	P=0.253N	P=0.088	P=0.137	P=0.180N
COCH-ARM / FISHERS	P=0.007N**	P=0.050*	P=0.107	P=0.024N*
MAX-ISO-POLY-3	P=0.050N*	P=0.055	P=0.094	P=0.107N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P<0.001**			
CURR VS HC ALL RTES	P=0.003**			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
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 Species/Strain: MICE/B6C3F1

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	24/50 (48%)	19/50 (38%)	23/50 (46%)	9/50 (18%)
POLY-3 RATE (b)	24/47.36	19/48.50	23/48.60	9/35.14
POLY-3 PERCENT (g)	50.7%	39.2%	47.3%	25.6%
TERMINAL (d)	16/36 (44%)	14/40 (35%)	19/42 (45%)	3/17 (18%)
FIRST INCIDENCE	499	644	592	252
HC TUMORS SAME ROUTE	146/250 (58%)			
HC TUMORS ALL ROUTES	276/550 (50%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.039N*	P=0.176N	P=0.451N	P=0.018N*
POLY 1.5	P=0.016N*	P=0.183N	P=0.461N	P=0.007N**
POLY 6	P=0.074N	P=0.169N	P=0.439N	P=0.038N*
COCH-ARM / FISHERS	P=0.002N**	P=0.210N	P=0.500N	P<0.001N**
MAX-ISO-POLY-3	P=0.042N*	P=0.131N	P=0.372N	P=0.020N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.135			
CURR VS HC ALL RTES	P=0.705			

Experiment Number: 20725 - 04  
 Test Type: CHRONIC  
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 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	Control	12.5 ppm	25 ppm	50 ppm
<b>All Organs</b>				
<b>Malignant and Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	34/50 (68%)	33/50 (66%)	34/50 (68%)	13/50 (26%)
POLY-3 RATE (b)	34/47.89	33/49.64	34/48.67	13/35.72
POLY-3 PERCENT (g)	71%	66.5%	69.9%	36.4%
TERMINAL (d)	24/36 (67%)	25/40 (63%)	29/42 (69%)	6/17 (35%)
FIRST INCIDENCE	499	561	592	252
HC TUMORS SAME ROUTE	199/250 (80%)			
HC TUMORS ALL ROUTES	404/550 (74%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.002N**	P=0.396N	P=0.540N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.422N	P=0.541N	P<0.001N**
POLY 6	P=0.011N*	P=0.369N	P=0.545N	P=0.004N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500N	P=0.585N	P<0.001N**
MAX-ISO-POLY-3	P=0.004N**	P=0.318N	P=0.450N	P=0.002N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.047*			
CURR VS HC ALL RTES	P=0.340			

**Experiment Number:** 20725 - 04  
**Test Type:** CHRONIC  
**Route:** RESPIRATORY EXPOSURE WHOLE BODY  
**Species/Strain:** MICE/B6C3F1

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

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