

**Experiment Number:** 05121-08  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

**Test Compound:** Scopolamine hydrobromide trihydrate

**CAS Number:** 6533-68-2

**Date Report Requested:** 10/16/2014

**Time Report Requested:** 06:36:50

**First Dose M/F:** NA / NA

**Lab:** BAT

<b>C Number:</b>	C03098C
<b>Lock Date:</b>	05/13/1992
<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>	03/13/1995

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**SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF SCOPOLAMINE HYDROBROMIDE**

**MALE MOUSE**

**Organ**

Adrenal Cortex: Capsule  
Bone Marrow: Erythroid Cell  
Bone Marrow: Myeloid Cell  
Islets, Pancreatic  
Preputial Gland: Duct  
Stomach, Forestomach  
Thyroid Gland: Follicular Cel

**FEMALE MOUSE**

**Organ**

Heart  
Kidney  
Liver  
Lung: Alveolar Epith  
Pancreas: Acinus  
Parathyroid Gland  
Spleen  
Thyroid Gland: Follicular Cel

**Morphology**

Hyperplasia Adenomatous  
Hyperplasia  
Hyperplasia  
Hyperplasia  
Ectasia  
Hyperplasia  
Hyperplasia

**Morphology**

Mineralization  
Nephropathy  
Basophilic Focus  
Hyperplasia  
Hyperplasia Focal  
Cyst  
Hyperplasia Lymphoid  
Hyperplasia

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Cortex</b>		
<b>Accessory Adrenal Cortical Nodule</b>		
<b>LESION RATES</b>		
OVERALL(a)	5/110 (5%)	1/110 (1%)
POLY-3 RATE (b)	5/102.01	1/99.88
POLY-3 PERCENT (g)	4.9%	1%
INT SACRIFICE 1	2/10 (20%)	0/10 (0%)
TERMINAL (d)	3/97 (3%)	1/97 (1%)
FIRST INCIDENCE	456(I)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.111N	P=0.111N
POLY 1.5	P=0.110N	P=0.110N
POLY 6	P=0.112N	P=0.112N
COCH-ARM / FISHERS	P=0.107N	P=0.106N
MAX-ISO-POLY-3	P=0.053N	P=0.053N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Cortex</b>		
<b>Angiectasis</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	0/110 (0%)
POLY-3 RATE (b)	0/100.52	0/99.88
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/97 (0%)	0/97 (0%)
FIRST INCIDENCE	---	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Cortex</b>		
<b>Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	20/110 (18%)	18/110 (16%)
POLY-3 RATE (b)	20/100.52	18/99.88
POLY-3 PERCENT (g)	19.9%	18%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	20/97 (21%)	18/97 (19%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.437N	P=0.437N
POLY 1.5	P=0.438N	P=0.438N
POLY 6	P=0.434N	P=0.434N
COCH-ARM / FISHERS	P=0.429N	P=0.429N
MAX-ISO-POLY-3	P=0.368N	P=0.368N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Cortex: Capsule Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	3/110 (3%)	1/110 (1%)
POLY-3 RATE (b)	3/100.52	1/99.88
POLY-3 PERCENT (g)	3%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	3/97 (3%)	1/97 (1%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.309N	P=0.309N
POLY 1.5	P=0.310N	P=0.310N
POLY 6	P=0.309N	P=0.309N
COCH-ARM / FISHERS	P=0.307N	P=0.311N
MAX-ISO-POLY-3	P=0.160N	P=0.160N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Cortex: Capsule</b>		
<b>Hyperplasia Adenomatous</b>		
<b>LESION RATES</b>		
OVERALL(a)	6/110 (5%)	0/110 (0%)
POLY-3 RATE (b)	6/100.52	0/99.88
POLY-3 PERCENT (g)	6%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	6/97 (6%)	0/97 (0%)
FIRST INCIDENCE	722(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.019N*	P=0.019N*
POLY 1.5	P=0.019N*	P=0.019N*
POLY 6	P=0.018N*	P=0.018N*
COCH-ARM / FISHERS	P=0.019N*	P=0.015N*
MAX-ISO-POLY-3	P=0.006N**	P=0.006N**
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Medulla</b>		
<b>Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	3/110 (3%)	1/109 (1%)
POLY-3 RATE (b)	3/100.52	1/98.88
POLY-3 PERCENT (g)	3%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	3/97 (3%)	1/96 (1%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.313N	P=0.313N
POLY 1.5	P=0.313N	P=0.313N
POLY 6	P=0.312N	P=0.312N
COCH-ARM / FISHERS	P=0.310N	P=0.314N
MAX-ISO-POLY-3	P=0.163N	P=0.163N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Blood Vessel: Aorta</b>		
<b>Thrombosis</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	0/110 (0%)
POLY-3 RATE (b)	0/100.52	0/99.88
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/97 (0%)	0/97 (0%)
FIRST INCIDENCE	---	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Bone Marrow</b>		
<b>Myelofibrosis</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/110 (2%)	0/110 (0%)
POLY-3 RATE (b)	2/100.52	0/99.88
POLY-3 PERCENT (g)	2%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/97 (2%)	0/97 (0%)
FIRST INCIDENCE	722(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.240N	P=0.240N
POLY 1.5	P=0.240N	P=0.240N
POLY 6	P=0.240N	P=0.240N
COCH-ARM / FISHERS	P=0.239N	P=0.249N
MAX-ISO-POLY-3	P=0.079N	P=0.079N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Species/Strain: Mouse/B6C3F1

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First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS**

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Bone Marrow: Erythroid Cell Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	3/110 (3%)
POLY-3 RATE (b)	0/100.52	3/99.88
POLY-3 PERCENT (g)	0%	3%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/97 (0%)	3/97 (3%)
FIRST INCIDENCE	---	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.121	P=0.121
POLY 1.5	P=0.121	P=0.121
POLY 6	P=0.121	P=0.121
COCH-ARM / FISHERS	P=0.122	P=0.123
MAX-ISO-POLY-3	P=0.040*	P=0.040*
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Species/Strain: Mouse/B6C3F1

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First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS**

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Bone Marrow: Myeloid Cell Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	6/110 (5%)	1/110 (1%)
POLY-3 RATE (b)	6/100.52	1/99.88
POLY-3 PERCENT (g)	6%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	6/97 (6%)	1/97 (1%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.062N	P=0.062N
POLY 1.5	P=0.062N	P=0.062N
POLY 6	P=0.062N	P=0.062N
COCH-ARM / FISHERS	P=0.062N	P=0.060N
MAX-ISO-POLY-3	P=0.028N*	P=0.028N*
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Epididymis		
Granuloma Sperm		
<hr/>		
LESION RATES		
OVERALL(a)	7/110 (6%)	6/110 (5%)
POLY-3 RATE (b)	7/100.52	6/99.88
POLY-3 PERCENT (g)	7%	6%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	7/97 (7%)	6/97 (6%)
FIRST INCIDENCE	722(T)	722(T)
<hr/>		
STATISTICAL TESTS		
POLY 3	P=0.505N	P=0.505N
POLY 1.5	P=0.505N	P=0.505N
POLY 6	P=0.503N	P=0.503N
COCH-ARM / FISHERS	P=1.000N	P=0.500N
MAX-ISO-POLY-3	P=0.392N	P=0.392N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Eye: Lens		
Cataract		
<hr/>		
LESION RATES		
OVERALL(a)	1/1 (100%)	2/3 (67%)
POLY-3 RATE (b)	1/1.00	2/2.38
POLY-3 PERCENT (g)	100%	84%
INT SACRIFICE 1	0/0 (0%)	0/0 (0%)
TERMINAL (d)	0/0 (0%)	2/2 (100%)
FIRST INCIDENCE	1050	1086(T)
<hr/>		
STATISTICAL TESTS		
POLY 3	P=0.959N	P=0.959N
POLY 1.5	P=0.834N	P=0.834N
POLY 6	P=1.000N	P=1.000N
COCH-ARM / FISHERS	P=0.748N	P=0.750N
MAX-ISO-POLY-3	P=0.332N	P=0.332N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Harderian Gland</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/50 (4%)	2/49 (4%)
POLY-3 RATE (b)	2/48.50	2/48.00
POLY-3 PERCENT (g)	4.1%	4.2%
INT SACRIFICE 1	2/4 (50%)	2/2 (100%)
TERMINAL (d)	0/46 (0%)	0/46 (0%)
FIRST INCIDENCE	456(l)	456(l)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.690	P=0.690
POLY 1.5	P=0.686	P=0.686
POLY 6	P=0.692	P=0.692
COCH-ARM / FISHERS	P=0.688	P=0.684
MAX-ISO-POLY-3	P=0.496	P=0.496
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Heart</b>		
<b>Mineralization</b>		
<b>LESION RATES</b>		
OVERALL(a)	1/110 (1%)	1/110 (1%)
POLY-3 RATE (b)	1/100.89	1/100.86
POLY-3 PERCENT (g)	1%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/97 (0%)	0/97 (0%)
FIRST INCIDENCE	620	214
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---



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Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Intestine Small, Jejunum</b>		
<b>Hyperplasia Lymphoid</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/110 (2%)	6/109 (6%)
POLY-3 RATE (b)	2/100.52	6/98.88
POLY-3 PERCENT (g)	2%	6.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/97 (2%)	6/96 (6%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.134	P=0.134
POLY 1.5	P=0.134	P=0.134
POLY 6	P=0.135	P=0.135
COCH-ARM / FISHERS	P=0.137	P=0.137
MAX-ISO-POLY-3	P=0.072	P=0.072
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Islets, Pancreatic Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	4/110 (4%)	0/109 (0%)
POLY-3 RATE (b)	4/100.52	0/98.88
POLY-3 PERCENT (g)	4%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	4/97 (4%)	0/96 (0%)
FIRST INCIDENCE	722(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.066N	P=0.066N
POLY 1.5	P=0.066N	P=0.066N
POLY 6	P=0.066N	P=0.066N
COCH-ARM / FISHERS	P=0.066N	P=0.062N
MAX-ISO-POLY-3	P=0.023N*	P=0.023N*
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Kidney</b>		
<b>Cyst</b>		
<b>LESION RATES</b>		
OVERALL(a)	3/110 (3%)	1/110 (1%)
POLY-3 RATE (b)	3/100.52	1/99.88
POLY-3 PERCENT (g)	3%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	3/97 (3%)	1/97 (1%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.309N	P=0.309N
POLY 1.5	P=0.310N	P=0.310N
POLY 6	P=0.309N	P=0.309N
COCH-ARM / FISHERS	P=0.307N	P=0.311N
MAX-ISO-POLY-3	P=0.160N	P=0.160N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Kidney</b>		
<b>Nephropathy</b>		
<b>LESION RATES</b>		
OVERALL(a)	96/110 (87%)	90/110 (82%)
POLY-3 RATE (b)	96/107.25	90/103.62
POLY-3 PERCENT (g)	89.5%	86.9%
INT SACRIFICE 1	9/10 (90%)	5/10 (50%)
TERMINAL (d)	87/97 (90%)	85/97 (88%)
FIRST INCIDENCE	456(I)	456(I)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.346N	P=0.346N
POLY 1.5	P=0.286N	P=0.286N
POLY 6	P=0.386N	P=0.386N
COCH-ARM / FISHERS	P=0.176N	P=0.176N
MAX-ISO-POLY-3	P=0.272N	P=0.272N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
Liver		
Basophilic Focus		
LESION RATES		
OVERALL(a)	1/110 (1%)	1/110 (1%)
POLY-3 RATE (b)	1/100.52	1/99.88
POLY-3 PERCENT (g)	1%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/97 (1%)	1/97 (1%)
FIRST INCIDENCE	722(T)	722(T)
STATISTICAL TESTS		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
Liver		
Clear Cell Focus		
<b>LESION RATES</b>		
OVERALL(a)	1/110 (1%)	0/110 (0%)
POLY-3 RATE (b)	1/100.52	0/99.88
POLY-3 PERCENT (g)	1%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/97 (1%)	0/97 (0%)
FIRST INCIDENCE	722(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Liver		
Eosinophilic Focus		
<hr/>		
LESION RATES		
OVERALL(a)	2/110 (2%)	1/110 (1%)
POLY-3 RATE (b)	2/100.52	1/99.88
POLY-3 PERCENT (g)	2%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/97 (2%)	1/97 (1%)
FIRST INCIDENCE	722(T)	722(T)
<hr/>		
STATISTICAL TESTS		
POLY 3	P=0.502N	P=0.502N
POLY 1.5	P=0.502N	P=0.502N
POLY 6	P=0.501N	P=0.501N
COCH-ARM / FISHERS	P=1.000N	P=0.500N
MAX-ISO-POLY-3	P=0.283N	P=0.283N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
Liver		
Hematopoietic Cell Proliferation		
<b>LESION RATES</b>		
OVERALL(a)	1/110 (1%)	0/110 (0%)
POLY-3 RATE (b)	1/100.52	0/99.88
POLY-3 PERCENT (g)	1%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/97 (1%)	0/97 (0%)
FIRST INCIDENCE	722(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---



Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Date Report Requested: 10/16/2014

Time Report Requested: 06:36:50

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS**

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Liver		
Hyperplasia Lymphoid		
<hr/>		
<b>LESION RATES</b>		
OVERALL(a)	2/110 (2%)	0/110 (0%)
POLY-3 RATE (b)	2/100.52	0/99.88
POLY-3 PERCENT (g)	2%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/97 (2%)	0/97 (0%)
FIRST INCIDENCE	722(T)	---
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.240N	P=0.240N
POLY 1.5	P=0.240N	P=0.240N
POLY 6	P=0.240N	P=0.240N
COCH-ARM / FISHERS	P=0.239N	P=0.249N
MAX-ISO-POLY-3	P=0.079N	P=0.079N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Liver		
Mixed Cell Focus		
<hr/>		
LESION RATES		
OVERALL(a)	2/110 (2%)	1/110 (1%)
POLY-3 RATE (b)	2/100.52	1/99.88
POLY-3 PERCENT (g)	2%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/97 (2%)	1/97 (1%)
FIRST INCIDENCE	722(T)	722(T)
<hr/>		
STATISTICAL TESTS		
POLY 3	P=0.502N	P=0.502N
POLY 1.5	P=0.502N	P=0.502N
POLY 6	P=0.501N	P=0.501N
COCH-ARM / FISHERS	P=1.000N	P=0.500N
MAX-ISO-POLY-3	P=0.283N	P=0.283N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Liver		
Necrosis		
<hr/>		
LESION RATES		
OVERALL(a)	2/110 (2%)	1/110 (1%)
POLY-3 RATE (b)	2/100.89	1/99.88
POLY-3 PERCENT (g)	2%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/97 (1%)	1/97 (1%)
FIRST INCIDENCE	620	722(T)
<hr/>		
STATISTICAL TESTS		
POLY 3	P=0.503N	P=0.503N
POLY 1.5	P=0.503N	P=0.503N
POLY 6	P=0.504N	P=0.504N
COCH-ARM / FISHERS	P=1.000N	P=0.500N
MAX-ISO-POLY-3	P=0.285N	P=0.285N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Liver: Bile Duct</b>		
<b>Cyst</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	2/110 (2%)
POLY-3 RATE (b)	0/100.52	2/99.88
POLY-3 PERCENT (g)	0%	2%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/97 (0%)	2/97 (2%)
FIRST INCIDENCE	---	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.237	P=0.237
POLY 1.5	P=0.237	P=0.237
POLY 6	P=0.238	P=0.238
COCH-ARM / FISHERS	P=0.239	P=0.249
MAX-ISO-POLY-3	P=0.078	P=0.078
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Lung</b>		
<b>Infiltration Cellular Histiocyte</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	0/110 (0%)
POLY-3 RATE (b)	0/100.52	0/99.88
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/97 (0%)	0/97 (0%)
FIRST INCIDENCE	---	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Lung</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	0/110 (0%)
POLY-3 RATE (b)	0/100.52	0/99.88
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/97 (0%)	0/97 (0%)
FIRST INCIDENCE	---	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Lung: Alveolar Epith Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	9/110 (8%)	8/110 (7%)
POLY-3 RATE (b)	9/100.52	8/99.88
POLY-3 PERCENT (g)	9%	8%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	9/97 (9%)	8/97 (8%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.505N	P=0.505N
POLY 1.5	P=0.506N	P=0.506N
POLY 6	P=0.504N	P=0.504N
COCH-ARM / FISHERS	P=1.000N	P=0.500N
MAX-ISO-POLY-3	P=0.406N	P=0.406N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Lymph Node, Mandibular Hyperplasia Lymphoid</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/108 (0%)	1/106 (1%)
POLY-3 RATE (b)	0/98.52	1/95.88
POLY-3 PERCENT (g)	0%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/95 (0%)	1/93 (1%)
FIRST INCIDENCE	---	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Lymph Node, Mesenteric</b>		
<b>Angiectasis</b>		
<b>LESION RATES</b>		
OVERALL(a)	5/109 (5%)	5/105 (5%)
POLY-3 RATE (b)	5/99.89	5/94.88
POLY-3 PERCENT (g)	5%	5.3%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	5/97 (5%)	5/92 (5%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.595	P=0.595
POLY 1.5	P=0.597	P=0.597
POLY 6	P=0.594	P=0.594
COCH-ARM / FISHERS	P=0.604	P=0.602
MAX-ISO-POLY-3	P=0.468	P=0.468
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Date Report Requested: 10/16/2014

Time Report Requested: 06:36:50

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS**

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Lymph Node, Mesenteric Hyperplasia Lymphoid</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/109 (0%)	2/105 (2%)
POLY-3 RATE (b)	0/99.89	2/94.88
POLY-3 PERCENT (g)	0%	2.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/97 (0%)	2/92 (2%)
FIRST INCIDENCE	---	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.227	P=0.227
POLY 1.5	P=0.228	P=0.228
POLY 6	P=0.227	P=0.227
COCH-ARM / FISHERS	P=0.231	P=0.240
MAX-ISO-POLY-3	P=0.076	P=0.076
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Mesentery: Fat</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	3/6 (50%)	0/1 (0%)
POLY-3 RATE (b)	3/4.13	0/1.00
POLY-3 PERCENT (g)	72.6%	0%
INT SACRIFICE 1	0/0 (0%)	0/0 (0%)
TERMINAL (d)	2/2 (100%)	0/1 (0%)
FIRST INCIDENCE	1020	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.402N	P=0.402N
POLY 1.5	P=0.478N	P=0.478N
POLY 6	P=0.273N	P=0.273N
COCH-ARM / FISHERS	P=0.562N	P=0.571N
MAX-ISO-POLY-3	P=0.079N	P=0.079N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Mesentery: Fat</b>		
<b>Necrosis</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/6 (33%)	0/1 (0%)
POLY-3 RATE (b)	2/4.31	0/1.00
POLY-3 PERCENT (g)	46.4%	0%
INT SACRIFICE 1	0/0 (0%)	0/0 (0%)
TERMINAL (d)	1/2 (50%)	0/1 (0%)
FIRST INCIDENCE	941	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.615N	P=0.615N
POLY 1.5	P=0.641N	P=0.641N
POLY 6	P=0.585N	P=0.585N
COCH-ARM / FISHERS	P=0.696N	P=0.714N
MAX-ISO-POLY-3	P=0.233N	P=0.233N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Pancreas: Acinus</b>		
<b>Atrophy</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/110 (2%)	1/110 (1%)
POLY-3 RATE (b)	2/100.52	1/99.88
POLY-3 PERCENT (g)	2%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/97 (2%)	1/97 (1%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.502N	P=0.502N
POLY 1.5	P=0.502N	P=0.502N
POLY 6	P=0.501N	P=0.501N
COCH-ARM / FISHERS	P=1.000N	P=0.500N
MAX-ISO-POLY-3	P=0.283N	P=0.283N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Pancreas: Acinus</b>		
<b>Hyperplasia Focal</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	1/110 (1%)
POLY-3 RATE (b)	0/100.52	1/99.88
POLY-3 PERCENT (g)	0%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/97 (0%)	1/97 (1%)
FIRST INCIDENCE	---	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Pancreas: Artery</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/110 (2%)	0/110 (0%)
POLY-3 RATE (b)	2/100.52	0/99.88
POLY-3 PERCENT (g)	2%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/97 (2%)	0/97 (0%)
FIRST INCIDENCE	722(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.240N	P=0.240N
POLY 1.5	P=0.240N	P=0.240N
POLY 6	P=0.240N	P=0.240N
COCH-ARM / FISHERS	P=0.239N	P=0.249N
MAX-ISO-POLY-3	P=0.079N	P=0.079N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Pancreas: Duct Ectasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	1/110 (1%)	0/110 (0%)
POLY-3 RATE (b)	1/100.52	0/99.88
POLY-3 PERCENT (g)	1%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/97 (1%)	0/97 (0%)
FIRST INCIDENCE	722(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---



Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Parathyroid Gland</b>		
<b>Cyst</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/99 (0%)	1/101 (1%)
POLY-3 RATE (b)	0/91.76	1/92.86
POLY-3 PERCENT (g)	0%	1.1%
INT SACRIFICE 1	0/7 (0%)	0/10 (0%)
TERMINAL (d)	0/89 (0%)	1/90 (1%)
FIRST INCIDENCE	---	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:50  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Pituitary Gland: Pars Distalis</b>		
<b>Cyst</b>		
<b>LESION RATES</b>		
OVERALL(a)	3/105 (3%)	1/85 (1%)
POLY-3 RATE (b)	3/95.89	1/76.38
POLY-3 PERCENT (g)	3.1%	1.3%
INT SACRIFICE 1	0/10 (0%)	0/8 (0%)
TERMINAL (d)	3/93 (3%)	1/74 (1%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.391N	P=0.391N
POLY 1.5	P=0.390N	P=0.390N
POLY 6	P=0.391N	P=0.391N
COCH-ARM / FISHERS	P=0.384N	P=0.394N
MAX-ISO-POLY-3	P=0.229N	P=0.229N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Pituitary Gland: Pars Distalis</b>		
<b>Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/105 (2%)	3/85 (4%)
POLY-3 RATE (b)	2/95.89	3/76.38
POLY-3 PERCENT (g)	2.1%	3.9%
INT SACRIFICE 1	0/10 (0%)	0/8 (0%)
TERMINAL (d)	2/93 (2%)	3/74 (4%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.398	P=0.398
POLY 1.5	P=0.399	P=0.399
POLY 6	P=0.398	P=0.398
COCH-ARM / FISHERS	P=0.405	P=0.401
MAX-ISO-POLY-3	P=0.251	P=0.251
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Preputial Gland</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	9/110 (8%)	7/109 (6%)
POLY-3 RATE (b)	9/100.52	7/98.88
POLY-3 PERCENT (g)	9%	7.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	9/97 (9%)	7/96 (7%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.411N	P=0.411N
POLY 1.5	P=0.411N	P=0.411N
POLY 6	P=0.409N	P=0.409N
COCH-ARM / FISHERS	P=0.405N	P=0.405N
MAX-ISO-POLY-3	P=0.314N	P=0.314N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Date Report Requested: 10/16/2014

Time Report Requested: 06:36:51

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS**

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MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Preputial Gland: Duct Ectasia		
<hr/>		
<b>LESION RATES</b>		
OVERALL(a)	48/110 (44%)	25/109 (23%)
POLY-3 RATE (b)	48/100.52	25/98.88
POLY-3 PERCENT (g)	47.8%	25.3%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	48/97 (49%)	25/96 (26%)
FIRST INCIDENCE	722(T)	722(T)
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.001N**	P=0.001N**
POLY 1.5	P=0.001N**	P=0.001N**
POLY 6	P=0.001N**	P=0.001N**
COCH-ARM / FISHERS	P=0.001N**	P=0.001N**
MAX-ISO-POLY-3	P=0.000N**	P=0.000N**
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Skin: Subcut Tiss</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/108 (2%)	0/110 (0%)
POLY-3 RATE (b)	2/98.52	0/99.88
POLY-3 PERCENT (g)	2%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/95 (2%)	0/97 (0%)
FIRST INCIDENCE	722(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.236N	P=0.236N
POLY 1.5	P=0.236N	P=0.236N
POLY 6	P=0.235N	P=0.235N
COCH-ARM / FISHERS	P=0.235N	P=0.244N
MAX-ISO-POLY-3	P=0.077N	P=0.077N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Spleen</b>		
<b>Depletion Lymphoid</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/110 (2%)	2/110 (2%)
POLY-3 RATE (b)	2/100.89	2/100.88
POLY-3 PERCENT (g)	2%	2%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/97 (1%)	1/97 (1%)
FIRST INCIDENCE	620	63
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.692	P=0.692
POLY 1.5	P=0.692N	P=0.692N
POLY 6	P=0.692	P=0.692
COCH-ARM / FISHERS	P=0.693	P=0.689N
MAX-ISO-POLY-3	P=0.500	P=0.500
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Spleen</b>		
<b>Hematopoietic Cell Proliferation</b>		
<b>LESION RATES</b>		
OVERALL(a)	17/110 (15%)	12/110 (11%)
POLY-3 RATE (b)	17/101.16	12/99.88
POLY-3 PERCENT (g)	16.8%	12%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	16/97 (16%)	12/97 (12%)
FIRST INCIDENCE	515	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.222N	P=0.222N
POLY 1.5	P=0.221N	P=0.221N
POLY 6	P=0.222N	P=0.222N
COCH-ARM / FISHERS	P=0.213N	P=0.213N
MAX-ISO-POLY-3	P=0.169N	P=0.169N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---



Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Spleen</b>		
<b>Hyperplasia Lymphoid</b>		
<b>LESION RATES</b>		
OVERALL(a)	1/110 (1%)	1/110 (1%)
POLY-3 RATE (b)	1/100.52	1/99.88
POLY-3 PERCENT (g)	1%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/97 (1%)	1/97 (1%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Stomach, Forestomach</b>		
<b>Cyst</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	2/110 (2%)
POLY-3 RATE (b)	0/100.52	2/99.88
POLY-3 PERCENT (g)	0%	2%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/97 (0%)	2/97 (2%)
FIRST INCIDENCE	---	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.237	P=0.237
POLY 1.5	P=0.237	P=0.237
POLY 6	P=0.238	P=0.238
COCH-ARM / FISHERS	P=0.239	P=0.249
MAX-ISO-POLY-3	P=0.078	P=0.078
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Stomach, Forestomach</b>		
<b>Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	3/110 (3%)
POLY-3 RATE (b)	0/100.52	3/99.88
POLY-3 PERCENT (g)	0%	3%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/97 (0%)	3/97 (3%)
FIRST INCIDENCE	---	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.121	P=0.121
POLY 1.5	P=0.121	P=0.121
POLY 6	P=0.121	P=0.121
COCH-ARM / FISHERS	P=0.122	P=0.123
MAX-ISO-POLY-3	P=0.040*	P=0.040*
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Stomach, Forestomach</b>		
<b>Hyperplasia Focal</b>		
<b>LESION RATES</b>		
OVERALL(a)	69/110 (63%)	71/110 (65%)
POLY-3 RATE (b)	69/105.37	71/106.03
POLY-3 PERCENT (g)	65.5%	67%
INT SACRIFICE 1	6/10 (60%)	6/10 (60%)
TERMINAL (d)	62/97 (64%)	63/97 (65%)
FIRST INCIDENCE	456(l)	63
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.467	P=0.467
POLY 1.5	P=0.461	P=0.461
POLY 6	P=0.476	P=0.476
COCH-ARM / FISHERS	P=0.444	P=0.444
MAX-ISO-POLY-3	P=0.410	P=0.410
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Stomach, Glandular</b>		
<b>Dysplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/110 (2%)	5/110 (5%)
POLY-3 RATE (b)	2/100.52	5/100.63
POLY-3 PERCENT (g)	2%	5%
INT SACRIFICE 1	0/10 (0%)	1/10 (10%)
TERMINAL (d)	2/97 (2%)	4/97 (4%)
FIRST INCIDENCE	722(T)	456(I)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.222	P=0.222
POLY 1.5	P=0.220	P=0.220
POLY 6	P=0.223	P=0.223
COCH-ARM / FISHERS	P=0.221	P=0.223
MAX-ISO-POLY-3	P=0.126	P=0.126
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Testes</b>		
<b>Atrophy</b>		
<b>LESION RATES</b>		
OVERALL(a)	10/110 (9%)	7/110 (6%)
POLY-3 RATE (b)	10/100.52	7/99.88
POLY-3 PERCENT (g)	9.9%	7%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	10/97 (10%)	7/97 (7%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.311N	P=0.311N
POLY 1.5	P=0.312N	P=0.312N
POLY 6	P=0.310N	P=0.310N
COCH-ARM / FISHERS	P=0.307N	P=0.307N
MAX-ISO-POLY-3	P=0.229N	P=0.229N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Thymus</b>		
<b>Atrophy</b>		
<b>LESION RATES</b>		
OVERALL(a)	13/89 (15%)	10/93 (11%)
POLY-3 RATE (b)	13/79.89	10/84.86
POLY-3 PERCENT (g)	16.3%	11.8%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	13/77 (17%)	10/82 (12%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.273N	P=0.273N
POLY 1.5	P=0.275N	P=0.275N
POLY 6	P=0.271N	P=0.271N
COCH-ARM / FISHERS	P=0.288N	P=0.288N
MAX-ISO-POLY-3	P=0.208N	P=0.208N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
Thymus		
Hyperplasia Lymphoid		
LESION RATES		
OVERALL(a)	0/89 (0%)	0/93 (0%)
POLY-3 RATE (b)	0/79.89	0/84.86
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/77 (0%)	0/82 (0%)
FIRST INCIDENCE	---	---
STATISTICAL TESTS		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---



Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Date Report Requested: 10/16/2014

Time Report Requested: 06:36:51

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS**

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Thyroid Gland: Follicular Cel Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	7/110 (6%)	2/110 (2%)
POLY-3 RATE (b)	7/100.52	2/99.88
POLY-3 PERCENT (g)	7%	2%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	7/97 (7%)	2/97 (2%)
FIRST INCIDENCE	722(T)	722(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.087N	P=0.087N
POLY 1.5	P=0.087N	P=0.087N
POLY 6	P=0.087N	P=0.087N
COCH-ARM / FISHERS	P=0.087N	P=0.085N
MAX-ISO-POLY-3	P=0.045N*	P=0.045N*
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Date Report Requested: 10/16/2014

Time Report Requested: 06:36:51

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 153 WEEKS**

---

MALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Tooth		
Dysplasia		
<hr/>		
<b>LESION RATES</b>		
OVERALL(a)	5/5 (100%)	6/7 (86%)
POLY-3 RATE (b)	5/5.00	6/7.00
POLY-3 PERCENT (g)	100%	85.7%
INT SACRIFICE 1	0/0 (0%)	0/0 (0%)
TERMINAL (d)	5/5 (100%)	6/7 (86%)
FIRST INCIDENCE	722(T)	722(T)
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.566N	P=0.566N
POLY 1.5	P=0.566N	P=0.566N
POLY 6	P=0.566N	P=0.566N
COCH-ARM / FISHERS	P=0.570N	P=0.583N
MAX-ISO-POLY-3	P=0.220N	P=0.220N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Cortex</b>		
<b>Accessory Adrenal Cortical Nodule</b>		
<b>LESION RATES</b>		
OVERALL(a)	1/109 (1%)	2/110 (2%)
POLY-3 RATE (b)	1/98.42	2/97.40
POLY-3 PERCENT (g)	1%	2.1%
INT SACRIFICE 1	1/10 (10%)	0/10 (0%)
TERMINAL (d)	0/91 (0%)	2/89 (2%)
FIRST INCIDENCE	456(I)	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.496	P=0.496
POLY 1.5	P=0.497	P=0.497
POLY 6	P=0.496	P=0.496
COCH-ARM / FISHERS	P=0.503	P=0.503
MAX-ISO-POLY-3	P=0.279	P=0.279
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Cortex</b>		
<b>Angiectasis</b>		
<b>LESION RATES</b>		
OVERALL(a)	1/109 (1%)	2/110 (2%)
POLY-3 RATE (b)	1/97.67	2/97.40
POLY-3 PERCENT (g)	1%	2.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/91 (1%)	2/89 (2%)
FIRST INCIDENCE	723(T)	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.499	P=0.499
POLY 1.5	P=0.499	P=0.499
POLY 6	P=0.500	P=0.500
COCH-ARM / FISHERS	P=0.503	P=0.503
MAX-ISO-POLY-3	P=0.281	P=0.281
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Cortex</b>		
<b>Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	4/109 (4%)	3/110 (3%)
POLY-3 RATE (b)	4/97.67	3/97.40
POLY-3 PERCENT (g)	4.1%	3.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	4/91 (4%)	3/89 (3%)
FIRST INCIDENCE	723(T)	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.501N	P=0.501N
POLY 1.5	P=0.502N	P=0.502N
POLY 6	P=0.501N	P=0.501N
COCH-ARM / FISHERS	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.353N	P=0.353N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Cortex: Capsule Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	1/109 (1%)	0/110 (0%)
POLY-3 RATE (b)	1/97.67	0/97.40
POLY-3 PERCENT (g)	1%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/91 (1%)	0/89 (0%)
FIRST INCIDENCE	723(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Cortex: Capsule Hyperplasia Adenomatous</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/109 (0%)	0/110 (0%)
POLY-3 RATE (b)	0/97.67	0/97.40
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/91 (0%)	0/89 (0%)
FIRST INCIDENCE	---	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Adrenal Medulla</b>		
<b>Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/108 (0%)	1/110 (1%)
POLY-3 RATE (b)	0/97.22	1/97.40
POLY-3 PERCENT (g)	0%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/91 (0%)	1/89 (1%)
FIRST INCIDENCE	---	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Blood Vessel: Aorta</b>		
<b>Thrombosis</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/110 (2%)	0/110 (0%)
POLY-3 RATE (b)	2/98.67	0/97.40
POLY-3 PERCENT (g)	2%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/92 (2%)	0/89 (0%)
FIRST INCIDENCE	723(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.241N	P=0.241N
POLY 1.5	P=0.241N	P=0.241N
POLY 6	P=0.241N	P=0.241N
COCH-ARM / FISHERS	P=0.239N	P=0.249N
MAX-ISO-POLY-3	P=0.081N	P=0.081N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Bone Marrow</b>		
<b>Myelofibrosis</b>		
<b>LESION RATES</b>		
OVERALL(a)	26/110 (24%)	26/110 (24%)
POLY-3 RATE (b)	26/98.87	26/97.40
POLY-3 PERCENT (g)	26.3%	26.7%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	25/92 (27%)	26/89 (29%)
FIRST INCIDENCE	673	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.540	P=0.540
POLY 1.5	P=0.541	P=0.541
POLY 6	P=0.538	P=0.538
COCH-ARM / FISHERS	P=0.563	P=0.563N
MAX-ISO-POLY-3	P=0.475	P=0.475
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Bone Marrow: Erythroid Cell Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	4/110 (4%)	2/110 (2%)
POLY-3 RATE (b)	4/99.22	2/97.72
POLY-3 PERCENT (g)	4%	2%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	3/92 (3%)	0/89 (0%)
FIRST INCIDENCE	555	666
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.347N	P=0.347N
POLY 1.5	P=0.346N	P=0.346N
POLY 6	P=0.346N	P=0.346N
COCH-ARM / FISHERS	P=0.339N	P=0.342N
MAX-ISO-POLY-3	P=0.211N	P=0.211N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Bone Marrow: Myeloid Cell Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	10/110 (9%)	8/110 (7%)
POLY-3 RATE (b)	10/99.22	8/98.45
POLY-3 PERCENT (g)	10.1%	8.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	9/92 (10%)	5/89 (6%)
FIRST INCIDENCE	555	561
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.409N	P=0.409N
POLY 1.5	P=0.411N	P=0.411N
POLY 6	P=0.405N	P=0.405N
COCH-ARM / FISHERS	P=0.403N	P=0.403N
MAX-ISO-POLY-3	P=0.317N	P=0.317N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Clitoral Gland: Duct Ectasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/109 (2%)	0/107 (0%)
POLY-3 RATE (b)	2/97.67	0/94.40
POLY-3 PERCENT (g)	2%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/91 (2%)	0/86 (0%)
FIRST INCIDENCE	723(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.246N	P=0.246N
POLY 1.5	P=0.246N	P=0.246N
POLY 6	P=0.246N	P=0.246N
COCH-ARM / FISHERS	P=0.243N	P=0.253N
MAX-ISO-POLY-3	P=0.084N	P=0.084N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Eye: Lens</b>		
<b>Cataract</b>		
<b>LESION RATES</b>		
OVERALL(a)	1/1 (100%)	3/3 (100%)
POLY-3 RATE (b)	1/1.00	3/3.00
POLY-3 PERCENT (g)	100%	100%
INT SACRIFICE 1	0/0 (0%)	0/0 (0%)
TERMINAL (d)	0/0 (0%)	1/1 (100%)
FIRST INCIDENCE	1085	961
<b>STATISTICAL TESTS</b>		
POLY 3	(e)	(e)
POLY 1.5	(e)	(e)
POLY 6	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Harderian Gland</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/46 (0%)	1/51 (2%)
POLY-3 RATE (b)	0/45.41	1/47.83
POLY-3 PERCENT (g)	0%	2.1%
INT SACRIFICE 1	0/0 (0%)	1/3 (33%)
TERMINAL (d)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	456(l)
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Heart</b>		
<b>Mineralization</b>		
<b>LESION RATES</b>		
OVERALL(a)	3/110 (3%)	0/110 (0%)
POLY-3 RATE (b)	3/99.22	0/97.40
POLY-3 PERCENT (g)	3%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/92 (2%)	0/89 (0%)
FIRST INCIDENCE	555	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.125N	P=0.125N
POLY 1.5	P=0.125N	P=0.125N
POLY 6	P=0.125N	P=0.125N
COCH-ARM / FISHERS	P=0.122N	P=0.123N
MAX-ISO-POLY-3	P=0.043N*	P=0.043N*
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Intestine Small, Jejunum</b>		
<b>Hyperplasia Lymphoid</b>		
<b>LESION RATES</b>		
OVERALL(a)	1/110 (1%)	0/109 (0%)
POLY-3 RATE (b)	1/98.67	0/96.40
POLY-3 PERCENT (g)	1%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/92 (1%)	0/88 (0%)
FIRST INCIDENCE	723(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Islets, Pancreatic Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	1/109 (1%)	0/110 (0%)
POLY-3 RATE (b)	1/97.87	0/97.40
POLY-3 PERCENT (g)	1%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/92 (1%)	0/89 (0%)
FIRST INCIDENCE	723(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Kidney</b>		
<b>Cyst</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	0/110 (0%)
POLY-3 RATE (b)	0/98.67	0/97.40
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/92 (0%)	0/89 (0%)
FIRST INCIDENCE	---	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Kidney</b>		
<b>Nephropathy</b>		
<b>LESION RATES</b>		
OVERALL(a)	35/110 (32%)	19/110 (17%)
POLY-3 RATE (b)	35/99.26	19/97.40
POLY-3 PERCENT (g)	35.3%	19.5%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	34/92 (37%)	19/89 (21%)
FIRST INCIDENCE	537	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.009N**	P=0.009N**
POLY 1.5	P=0.009N**	P=0.009N**
POLY 6	P=0.009N**	P=0.009N**
COCH-ARM / FISHERS	P=0.009N**	P=0.009N**
MAX-ISO-POLY-3	P=0.007N**	P=0.007N**
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
Liver		
Basophilic Focus		
LESION RATES		
OVERALL(a)	1/110 (1%)	5/110 (5%)
POLY-3 RATE (b)	1/98.67	5/98.15
POLY-3 PERCENT (g)	1%	5.1%
INT SACRIFICE 1	0/10 (0%)	1/10 (10%)
TERMINAL (d)	1/92 (1%)	4/89 (4%)
FIRST INCIDENCE	723(T)	456(I)
STATISTICAL TESTS		
POLY 3	P=0.105	P=0.105
POLY 1.5	P=0.105	P=0.105
POLY 6	P=0.106	P=0.106
COCH-ARM / FISHERS	P=0.107	P=0.106
MAX-ISO-POLY-3	P=0.048*	P=0.048*
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Liver		
Clear Cell Focus		
<hr/>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	2/110 (2%)
POLY-3 RATE (b)	0/98.67	2/97.40
POLY-3 PERCENT (g)	0%	2.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/92 (0%)	2/89 (2%)
FIRST INCIDENCE	---	723(T)
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.236	P=0.236
POLY 1.5	P=0.236	P=0.236
POLY 6	P=0.236	P=0.236
COCH-ARM / FISHERS	P=0.239	P=0.249
MAX-ISO-POLY-3	P=0.078	P=0.078
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Liver		
Eosinophilic Focus		
<hr/>		
LESION RATES		
OVERALL(a)	4/110 (4%)	1/110 (1%)
POLY-3 RATE (b)	4/98.67	1/97.40
POLY-3 PERCENT (g)	4.1%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	4/92 (4%)	1/89 (1%)
FIRST INCIDENCE	723(T)	723(T)
<hr/>		
STATISTICAL TESTS		
POLY 3	P=0.186N	P=0.186N
POLY 1.5	P=0.186N	P=0.186N
POLY 6	P=0.186N	P=0.186N
COCH-ARM / FISHERS	P=0.183N	P=0.185N
MAX-ISO-POLY-3	P=0.091N	P=0.091N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Liver		
Hematopoietic Cell Proliferation		
<hr/>		
LESION RATES		
OVERALL(a)	1/110 (1%)	2/110 (2%)
POLY-3 RATE (b)	1/99.07	2/97.48
POLY-3 PERCENT (g)	1%	2.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/92 (0%)	1/89 (1%)
FIRST INCIDENCE	611	703
<hr/>		
STATISTICAL TESTS		
POLY 3	P=0.494	P=0.494
POLY 1.5	P=0.495	P=0.495
POLY 6	P=0.494	P=0.494
COCH-ARM / FISHERS	P=1.000	P=0.500
MAX-ISO-POLY-3	P=0.278	P=0.278
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---



Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
Liver		
Hyperplasia Lymphoid		
LESION RATES		
OVERALL(a)	1/110 (1%)	0/110 (0%)
POLY-3 RATE (b)	1/98.67	0/97.40
POLY-3 PERCENT (g)	1%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/92 (1%)	0/89 (0%)
FIRST INCIDENCE	723(T)	---
STATISTICAL TESTS		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Date Report Requested: 10/16/2014

Time Report Requested: 06:36:51

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS**

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Liver		
Mixed Cell Focus		
<hr/>		
<b>LESION RATES</b>		
OVERALL(a)	2/110 (2%)	1/110 (1%)
POLY-3 RATE (b)	2/98.67	1/97.40
POLY-3 PERCENT (g)	2%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/92 (2%)	1/89 (1%)
FIRST INCIDENCE	723(T)	723(T)
<hr/>		
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.504N	P=0.504N
POLY 1.5	P=0.504N	P=0.504N
POLY 6	P=0.504N	P=0.504N
COCH-ARM / FISHERS	P=1.000N	P=0.500N
MAX-ISO-POLY-3	P=0.286N	P=0.286N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Liver		
Necrosis		
<hr/>		
LESION RATES		
OVERALL(a)	2/110 (2%)	2/110 (2%)
POLY-3 RATE (b)	2/99.62	2/97.62
POLY-3 PERCENT (g)	2%	2%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/92 (0%)	1/89 (1%)
FIRST INCIDENCE	555	666
<hr/>		
STATISTICAL TESTS		
POLY 3	P=0.685	P=0.685
POLY 1.5	P=0.686	P=0.686
POLY 6	P=0.684	P=0.684
COCH-ARM / FISHERS	P=0.693	P=0.689N
MAX-ISO-POLY-3	P=0.492	P=0.492
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Liver: Bile Duct</b>		
<b>Cyst</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	2/110 (2%)
POLY-3 RATE (b)	0/98.67	2/97.40
POLY-3 PERCENT (g)	0%	2.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/92 (0%)	2/89 (2%)
FIRST INCIDENCE	---	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.236	P=0.236
POLY 1.5	P=0.236	P=0.236
POLY 6	P=0.236	P=0.236
COCH-ARM / FISHERS	P=0.239	P=0.249
MAX-ISO-POLY-3	P=0.078	P=0.078
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Lung</b>		
<b>Infiltration Cellular Histiocyte</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/110 (2%)	0/110 (0%)
POLY-3 RATE (b)	2/98.67	0/97.40
POLY-3 PERCENT (g)	2%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/92 (2%)	0/89 (0%)
FIRST INCIDENCE	723(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.241N	P=0.241N
POLY 1.5	P=0.241N	P=0.241N
POLY 6	P=0.241N	P=0.241N
COCH-ARM / FISHERS	P=0.239N	P=0.249N
MAX-ISO-POLY-3	P=0.081N	P=0.081N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Lung</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	2/110 (2%)
POLY-3 RATE (b)	0/98.67	2/98.15
POLY-3 PERCENT (g)	0%	2%
INT SACRIFICE 1	0/10 (0%)	1/10 (10%)
TERMINAL (d)	0/92 (0%)	1/89 (1%)
FIRST INCIDENCE	---	456(l)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.237	P=0.237
POLY 1.5	P=0.237	P=0.237
POLY 6	P=0.238	P=0.238
COCH-ARM / FISHERS	P=0.239	P=0.249
MAX-ISO-POLY-3	P=0.078	P=0.078
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Scopolamine hydrobromide trihydrate  
 CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
 Time Report Requested: 06:36:51  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 155 WEEKS**

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
Lung: Alveolar Epith Hyperplasia		
<b>LESION RATES</b>		
OVERALL(a)	1/110 (1%)	8/110 (7%)
POLY-3 RATE (b)	1/98.67	8/97.40
POLY-3 PERCENT (g)	1%	8.2%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/92 (1%)	8/89 (9%)
FIRST INCIDENCE	723(T)	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.018*	P=0.018*
POLY 1.5	P=0.019*	P=0.019*
POLY 6	P=0.018*	P=0.018*
COCH-ARM / FISHERS	P=0.021*	P=0.018*
MAX-ISO-POLY-3	P=0.008**	P=0.008**
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Lymph Node, Mandibular Hyperplasia Lymphoid</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/105 (2%)	1/105 (1%)
POLY-3 RATE (b)	2/93.67	1/92.70
POLY-3 PERCENT (g)	2.1%	1.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/87 (2%)	0/84 (0%)
FIRST INCIDENCE	723(T)	644
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.504N	P=0.504N
POLY 1.5	P=0.504N	P=0.504N
POLY 6	P=0.502N	P=0.502N
COCH-ARM / FISHERS	P=1.000N	P=0.500N
MAX-ISO-POLY-3	P=0.285N	P=0.285N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---



Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Lymph Node, Mesenteric</b>		
<b>Angiectasis</b>		
<b>LESION RATES</b>		
OVERALL(a)	3/94 (3%)	1/108 (1%)
POLY-3 RATE (b)	3/84.92	1/96.40
POLY-3 PERCENT (g)	3.5%	1%
INT SACRIFICE 1	0/7 (0%)	0/10 (0%)
TERMINAL (d)	3/79 (4%)	1/88 (1%)
FIRST INCIDENCE	723(T)	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.263N	P=0.263N
POLY 1.5	P=0.262N	P=0.262N
POLY 6	P=0.263N	P=0.263N
COCH-ARM / FISHERS	P=0.259N	P=0.260N
MAX-ISO-POLY-3	P=0.135N	P=0.135N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Lymph Node, Mesenteric Hyperplasia Lymphoid</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/94 (0%)	1/108 (1%)
POLY-3 RATE (b)	0/84.92	1/96.70
POLY-3 PERCENT (g)	0%	1%
INT SACRIFICE 1	0/7 (0%)	0/10 (0%)
TERMINAL (d)	0/79 (0%)	0/88 (0%)
FIRST INCIDENCE	---	644
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Mesentery: Fat</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/8 (0%)	0/6 (0%)
POLY-3 RATE (b)	0/5.98	0/5.47
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/0 (0%)	0/0 (0%)
TERMINAL (d)	0/4 (0%)	0/5 (0%)
FIRST INCIDENCE	---	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Mesentery: Fat</b>		
<b>Necrosis</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/8 (0%)	0/6 (0%)
POLY-3 RATE (b)	0/5.98	0/5.47
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/0 (0%)	0/0 (0%)
TERMINAL (d)	0/4 (0%)	0/5 (0%)
FIRST INCIDENCE	---	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Ovary</b>		
<b>Angiectasis</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/109 (2%)	2/109 (2%)
POLY-3 RATE (b)	2/98.22	2/96.40
POLY-3 PERCENT (g)	2%	2.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/91 (1%)	2/88 (2%)
FIRST INCIDENCE	555	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.686	P=0.686
POLY 1.5	P=0.687	P=0.687
POLY 6	P=0.685	P=0.685
COCH-ARM / FISHERS	P=0.693	P=0.689N
MAX-ISO-POLY-3	P=0.493	P=0.493
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

**Experiment Number:** 05121-08  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
**Test Compound:** Scopolamine hydrobromide trihydrate  
**CAS Number:** 6533-68-2

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 06:36:51  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)**  
**LAST REMOVAL AT 155 WEEKS**

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Ovary</b>		
<b>Cyst</b>		
<b>LESION RATES</b>		
<b>OVERALL(a)</b>	32/109 (29%)	28/109 (26%)
<b>POLY-3 RATE (b)</b>	32/99.16	28/96.62
<b>POLY-3 PERCENT (g)</b>	32.3%	29%
<b>INT SACRIFICE 1</b>	1/10 (10%)	0/10 (0%)
<b>TERMINAL (d)</b>	29/91 (32%)	27/88 (31%)
<b>FIRST INCIDENCE</b>	456(l)	666
<b>STATISTICAL TESTS</b>		
<b>POLY 3</b>	P=0.365N	P=0.365N
<b>POLY 1.5</b>	P=0.357N	P=0.357N
<b>POLY 6</b>	P=0.371N	P=0.371N
<b>COCH-ARM / FISHERS</b>	P=0.325N	P=0.325N
<b>MAX-ISO-POLY-3</b>	P=0.310N	P=0.310N
<b>HISTCONT SAME RTE</b>		
<b>HISTCONT ALL RTES</b>		
<b>CURR VS HC SAME RTE</b>		
<b>CURR VS HC ALL RTES</b>		

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Ovary</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/109 (2%)	0/109 (0%)
POLY-3 RATE (b)	2/97.67	0/96.40
POLY-3 PERCENT (g)	2%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/91 (2%)	0/88 (0%)
FIRST INCIDENCE	723(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.241N	P=0.241N
POLY 1.5	P=0.241N	P=0.241N
POLY 6	P=0.241N	P=0.241N
COCH-ARM / FISHERS	P=0.239N	P=0.249N
MAX-ISO-POLY-3	P=0.081N	P=0.081N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Scopolamine hydrobromide trihydrate

CAS Number: 6533-68-2

Date Report Requested: 10/16/2014

Time Report Requested: 06:36:51

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS**

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<b>FEMALE</b>		
<b>DOSE</b>	<b>0 MG/KG 20%/36M</b>	<b>25 MG/KG104/WEEK</b>
<b>Pancreas: Acinus</b>		
<b>Atrophy</b>		
<b>LESION RATES</b>		
<b>OVERALL(a)</b>	4/109 (4%)	6/110 (5%)
<b>POLY-3 RATE (b)</b>	4/97.67	6/97.40
<b>POLY-3 PERCENT (g)</b>	4.1%	6.2%
<b>INT SACRIFICE 1</b>	0/10 (0%)	0/10 (0%)
<b>TERMINAL (d)</b>	4/91 (4%)	6/89 (7%)
<b>FIRST INCIDENCE</b>	723(T)	723(T)
<b>STATISTICAL TESTS</b>		
<b>POLY 3</b>	P=0.371	P=0.371
<b>POLY 1.5</b>	P=0.371	P=0.371
<b>POLY 6</b>	P=0.372	P=0.372
<b>COCH-ARM / FISHERS</b>	P=0.379	P=0.380
<b>MAX-ISO-POLY-3</b>	P=0.258	P=0.258
<b>HISTCONT SAME RTE</b>		
<b>HISTCONT ALL RTES</b>		
<b>CURR VS HC SAME RTE</b>		
<b>CURR VS HC ALL RTES</b>		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Pancreas: Acinus</b>		
<b>Hyperplasia Focal</b>		
<b>LESION RATES</b>		
OVERALL(a)	3/109 (3%)	0/110 (0%)
POLY-3 RATE (b)	3/97.67	0/97.40
POLY-3 PERCENT (g)	3.1%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	3/91 (3%)	0/89 (0%)
FIRST INCIDENCE	723(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.122N	P=0.122N
POLY 1.5	P=0.122N	P=0.122N
POLY 6	P=0.122N	P=0.122N
COCH-ARM / FISHERS	P=0.121N	P=0.122N
MAX-ISO-POLY-3	P=0.041N*	P=0.041N*
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Pancreas: Artery</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	2/109 (2%)	0/110 (0%)
POLY-3 RATE (b)	2/97.67	0/97.40
POLY-3 PERCENT (g)	2%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	2/91 (2%)	0/89 (0%)
FIRST INCIDENCE	723(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.239N	P=0.239N
POLY 1.5	P=0.239N	P=0.239N
POLY 6	P=0.239N	P=0.239N
COCH-ARM / FISHERS	P=0.237N	P=0.247N
MAX-ISO-POLY-3	P=0.079N	P=0.079N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Pancreas: Duct Ectasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	1/109 (1%)	3/110 (3%)
POLY-3 RATE (b)	1/97.67	3/97.40
POLY-3 PERCENT (g)	1%	3.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/91 (1%)	3/89 (3%)
FIRST INCIDENCE	723(T)	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.306	P=0.306
POLY 1.5	P=0.306	P=0.306
POLY 6	P=0.307	P=0.307
COCH-ARM / FISHERS	P=0.310	P=0.314
MAX-ISO-POLY-3	P=0.157	P=0.157
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Parathyroid Gland</b>		
<b>Cyst</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/97 (0%)	3/95 (3%)
POLY-3 RATE (b)	0/87.72	3/84.65
POLY-3 PERCENT (g)	0%	3.5%
INT SACRIFICE 1	0/8 (0%)	1/8 (12%)
TERMINAL (d)	0/82 (0%)	2/76 (3%)
FIRST INCIDENCE	---	456(I)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.115	P=0.115
POLY 1.5	P=0.115	P=0.115
POLY 6	P=0.115	P=0.115
COCH-ARM / FISHERS	P=0.119	P=0.119
MAX-ISO-POLY-3	P=0.039*	P=0.039*
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Pituitary Gland: Pars Distalis</b>		
<b>Cyst</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/98 (0%)	0/105 (0%)
POLY-3 RATE (b)	0/87.20	0/92.40
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/81 (0%)	0/84 (0%)
FIRST INCIDENCE	---	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Pituitary Gland: Pars Distalis</b>		
<b>Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	10/98 (10%)	5/105 (5%)
POLY-3 RATE (b)	10/88.15	5/92.48
POLY-3 PERCENT (g)	11.3%	5.4%
INT SACRIFICE 1	1/10 (10%)	0/10 (0%)
TERMINAL (d)	8/81 (10%)	4/84 (5%)
FIRST INCIDENCE	456(l)	703
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.119N	P=0.119N
POLY 1.5	P=0.118N	P=0.118N
POLY 6	P=0.120N	P=0.120N
COCH-ARM / FISHERS	P=0.113N	P=0.112N
MAX-ISO-POLY-3	P=0.075N	P=0.075N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Skin: Subcut Tiss</b>		
<b>Inflammation Chronic</b>		
<b>LESION RATES</b>		
OVERALL(a)	1/110 (1%)	1/110 (1%)
POLY-3 RATE (b)	1/98.67	1/97.40
POLY-3 PERCENT (g)	1%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/92 (1%)	1/89 (1%)
FIRST INCIDENCE	723(T)	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Spleen</b>		
<b>Depletion Lymphoid</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	1/110 (1%)
POLY-3 RATE (b)	0/98.67	1/98.40
POLY-3 PERCENT (g)	0%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/92 (0%)	0/89 (0%)
FIRST INCIDENCE	---	13
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---



Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Spleen</b>		
<b>Hematopoietic Cell Proliferation</b>		
<b>LESION RATES</b>		
OVERALL(a)	24/110 (22%)	24/110 (22%)
POLY-3 RATE (b)	24/102.16	24/99.43
POLY-3 PERCENT (g)	23.5%	24.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	17/92 (18%)	18/89 (20%)
FIRST INCIDENCE	492	538
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.523	P=0.523
POLY 1.5	P=0.532	P=0.532
POLY 6	P=0.517	P=0.517
COCH-ARM / FISHERS	P=0.565	P=0.565N
MAX-ISO-POLY-3	P=0.458	P=0.458
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Scopolamine hydrobromide trihydrate  
 CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
 Time Report Requested: 06:36:51  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 155 WEEKS**

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Spleen</b>		
<b>Hyperplasia Lymphoid</b>		
<b>LESION RATES</b>		
OVERALL(a)	3/110 (3%)	0/110 (0%)
POLY-3 RATE (b)	3/98.67	0/97.40
POLY-3 PERCENT (g)	3%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	3/92 (3%)	0/89 (0%)
FIRST INCIDENCE	723(T)	---
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.124N	P=0.124N
POLY 1.5	P=0.124N	P=0.124N
POLY 6	P=0.124N	P=0.124N
COCH-ARM / FISHERS	P=0.122N	P=0.123N
MAX-ISO-POLY-3	P=0.042N*	P=0.042N*
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
Stomach, Forestomach		
Cyst		
LESION RATES		
OVERALL(a)	1/110 (1%)	0/110 (0%)
POLY-3 RATE (b)	1/98.67	0/97.40
POLY-3 PERCENT (g)	1%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	1/92 (1%)	0/89 (0%)
FIRST INCIDENCE	723(T)	---
STATISTICAL TESTS		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Stomach, Forestomach</b>		
<b>Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	0/110 (0%)
POLY-3 RATE (b)	0/98.67	0/97.40
POLY-3 PERCENT (g)	0%	0%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/92 (0%)	0/89 (0%)
FIRST INCIDENCE	---	---
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Stomach, Forestomach</b>		
<b>Hyperplasia Focal</b>		
<b>LESION RATES</b>		
OVERALL(a)	59/110 (54%)	66/110 (60%)
POLY-3 RATE (b)	59/105.25	66/103.77
POLY-3 PERCENT (g)	56.1%	63.6%
INT SACRIFICE 1	7/10 (70%)	6/10 (60%)
TERMINAL (d)	49/92 (53%)	56/89 (63%)
FIRST INCIDENCE	456(l)	400
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.163	P=0.163
POLY 1.5	P=0.168	P=0.168
POLY 6	P=0.161	P=0.161
COCH-ARM / FISHERS	P=0.207	P=0.207
MAX-ISO-POLY-3	P=0.133	P=0.133
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Stomach, Glandular</b>		
<b>Dysplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/110 (0%)	1/110 (1%)
POLY-3 RATE (b)	0/98.67	1/97.40
POLY-3 PERCENT (g)	0%	1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/92 (0%)	1/89 (1%)
FIRST INCIDENCE	---	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

---

Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Thymus</b>		
<b>Atrophy</b>		
<b>LESION RATES</b>		
OVERALL(a)	10/92 (11%)	6/101 (6%)
POLY-3 RATE (b)	10/82.45	6/89.97
POLY-3 PERCENT (g)	12.1%	6.7%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	10/77 (13%)	1/80 (1%)
FIRST INCIDENCE	723(T)	13
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.165N	P=0.165N
POLY 1.5	P=0.166N	P=0.166N
POLY 6	P=0.164N	P=0.164N
COCH-ARM / FISHERS	P=0.164N	P=0.164N
MAX-ISO-POLY-3	P=0.114N	P=0.114N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Thymus</b>		
<b>Hyperplasia Lymphoid</b>		
<b>LESION RATES</b>		
OVERALL(a)	0/92 (0%)	2/101 (2%)
POLY-3 RATE (b)	0/82.45	2/88.70
POLY-3 PERCENT (g)	0%	2.3%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/77 (0%)	1/80 (1%)
FIRST INCIDENCE	---	644
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.255	P=0.255
POLY 1.5	P=0.255	P=0.255
POLY 6	P=0.254	P=0.254
COCH-ARM / FISHERS	P=0.259	P=0.273
MAX-ISO-POLY-3	P=0.088	P=0.088
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
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Date Report Requested: 10/16/2014  
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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Thyroid Gland: Follicular Cel Hyperplasia</b>		
<b>LESION RATES</b>		
OVERALL(a)	11/110 (10%)	2/109 (2%)
POLY-3 RATE (b)	11/98.67	2/96.40
POLY-3 PERCENT (g)	11.1%	2.1%
INT SACRIFICE 1	0/10 (0%)	0/10 (0%)
TERMINAL (d)	11/92 (12%)	2/88 (2%)
FIRST INCIDENCE	723(T)	723(T)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.011N*	P=0.011N*
POLY 1.5	P=0.011N*	P=0.011N*
POLY 6	P=0.011N*	P=0.011N*
COCH-ARM / FISHERS	P=0.012N*	P=0.010N**
MAX-ISO-POLY-3	P=0.006N**	P=0.006N**
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
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Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

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FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<hr/>		
Tooth		
Dysplasia		
<hr/>		
LESION RATES		
OVERALL(a)	2/2 (100%)	1/2 (50%)
POLY-3 RATE (b)	2/2.00	1/1.89
POLY-3 PERCENT (g)	100%	52.9%
INT SACRIFICE 1	0/0 (0%)	0/0 (0%)
TERMINAL (d)	2/2 (100%)	1/1 (100%)
FIRST INCIDENCE	1087(T)	1087(T)
<hr/>		
STATISTICAL TESTS		
POLY 3	P=0.537N	P=0.537N
POLY 1.5	P=0.518N	P=0.518N
POLY 6	P=0.579N	P=0.579N
COCH-ARM / FISHERS	P=1.000N	P=0.500N
MAX-ISO-POLY-3	P=0.166N	P=0.166N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Experiment Number: 05121-08  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Test Compound: Scopolamine hydrobromide trihydrate  
CAS Number: 6533-68-2

Date Report Requested: 10/16/2014  
Time Report Requested: 06:36:51  
First Dose M/F: NA / NA  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 155 WEEKS

---

FEMALE		
DOSE	0 MG/KG 20%/36M	25 MG/KG104/WEEK
<b>Uterus</b>		
<b>Hyperplasia Cystic</b>		
<b>LESION RATES</b>		
OVERALL(a)	25/109 (23%)	28/109 (26%)
POLY-3 RATE (b)	25/97.67	28/100.09
POLY-3 PERCENT (g)	25.6%	28%
INT SACRIFICE 1	0/10 (0%)	2/10 (20%)
TERMINAL (d)	25/91 (27%)	23/89 (26%)
FIRST INCIDENCE	723(T)	456(I)
<b>STATISTICAL TESTS</b>		
POLY 3	P=0.414	P=0.414
POLY 1.5	P=0.396	P=0.396
POLY 6	P=0.436	P=0.436
COCH-ARM / FISHERS	P=0.376	P=0.376
MAX-ISO-POLY-3	P=0.354	P=0.354
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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**Experiment Number:** 05121-08  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

**Test Compound:** Scopolamine hydrobromide trihydrate

**CAS Number:** 6533-68-2

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 06:36:51  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (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 \*\***