Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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Report Date:04/29/2009

Study Summary

| Laboratory Name | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical |
|---|-------------------------------------|----------------------------------|----------------------------------|---|--|--|--|
| | | | | Ma | ale | | |
| Southern Research Institute Southern Research Institute Southern Research Institute | 059902408 059903706 059100508 | 12/16/02 06/30/03 07/10/00 | 729 729 729 | 50 (1) 50 (1) 50 (1) | 36(687) 40(701) 35(693) | 53.8 53.9 53.6 | Androstenedione alpha/beta Thujone mixture Methylene blue trihydrate |
| | | | | Fen | nale | | |
| Southern Research Institute Southern Research Institute Southern Research Institute | 059902408 059903706 059100508 | 12/16/02 06/30/03 07/10/00 | 733 731 732 | 50 (5) 50 (5) 50 (5) | 35(690) 37(668) 29(695) | 65.3 64.7 63.5 | Androstenedione alpha/beta Thujone mixture Methylene blue trihydrate |

Species: MICE

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Strain: B6C3F1 Length of Study: CHRONIC Vehicle: METHYLCELLULOSE

| | | | Male | | | | Female | |
|--------------------------------------|-------|---------------------------------|----------------------------|--------------------------|-------|--------------------------------|----------------------------|-------------------------|
| All Organs: Benign Tumors | | | | | | | | |
| Overall Incidence | Total | 38/50 (76%) 107/150 (71.33%) | 32/50 (64%) Mean 71.33% | 37/50 (74%) SD 6.43% | Total | 27/50 (54%) 74/150 (49.33%) | 22/50 (44%) Mean 49.33% | 25/50 (50%) SD 5.03% |
| All Organs: Malignant Tumors | | | | | | 27/50 (540/) | | |
| Overall Incidence | Total | 37/50 (74%) 93/150 (62%) | 30/50 (60%) Mean 62% | 26/50 (52%) SD 11.14% | Total | 27/50 (54%) 72/150 (48%) | 19/50 (38%) Mean 48% | 26/50 (52%) SD 8.72% |
| All Organs: Malignant and Benign Tu | mors | | | | ••••• | (000) | | |
| Overall Incidence | Total | 47/50 (94%) 138/150 (92%) | 45/50 (90%) Mean 92% | 46/50 (92%) SD 2% | Total | 40/50 (80%) 114/150 (76%) | 35/50 (70%) Mean 76% | 39/50 (78%) SD 5.29% |
| All Organs: Hemangioma | | | | | ••••• | | | |
| Overall Incidence | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 1/50 (2%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% | 1/50 (2%) SD 1.15% |
| All Organs: Hemangiosarcoma | | | | | ••••• | | | |
| Overall Incidence | Total | 5/50 (10%) 15/150 (10%) | 4/50 (8%) Mean 10% | 6/50 (12%) SD 2% | Total | 1/50 (2%) 5/150 (3.33%) | 1/50 (2%) Mean 3.33% | 3/50 (6%) SD 2.31% |
| All Organs: Hemangiosarcoma or He | | | | | | | | |
| Overall Incidence | Total | 5/50 (10%) 15/150 (10%) | 4/50 (8%) Mean 10% | 6/50 (12%) SD 2% | Total | 2/50 (4%) 7/150 (4.67%) | 1/50 (2%) Mean 4.67% | 4/50 (8%) SD 3.06% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|------------------|-----------------------------|-------------------------|-----------------------|-------|--------------------------------|---------------------------|------------------------|
| All Organs: Histiocytic Sarcoma | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 2/50 (4%) | 2/50 (4%) | 2/50 (4%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 6/150 (4%) | Mean 4% | SD 0% |
| All Organs: Malignant Lymphoma: or Undifferentiated Cell | Histiocytic, Lyn | nphocytic, Mixed, NOS, | | | | | | |
| verall Incidence | Total | 4/50 (8%) 10/150 (6.67%) | 4/50 (8%) Mean 6.67% | 2/50 (4%) SD 2.31% | Total | 14/50 (28%) 26/150 (17.33%) | 6/50 (12%) Mean 17.33% | 6/50 (12%) SD 9.24% |
| All Organs: Mesothelioma: Benign, | Malignant, NO | S 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| All Organs: Mesothelioma: Maligna | nt | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| All Organs: Osteoma | | 0/50 (00/) | 4/50 (00) | 0/50 (00) | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) |
| verall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| All Organs: Osteosarcoma | | 0/50 (00/) | | | | 4/50 (00/) | 0(50 (004) | 4/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/50 (2%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% | 1/50 (2%) SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | Female |
|---|-------|----------------------------|--|---|
| #All Organs: Osteosarcoma or Osteoma | | 0/50 (0%) | 4/50 (09) | 4/50 (20/) 0/50 (00/) 4/50 (20/) |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15% | 1/50 (2%) 0/50 (0%) 1/50 (2%) Total 2/150 (1.33%) Mean 1.33% SD 1.15% |
| *Adrenal Cortex: Adenoma | | 1/50 (2%) | 2/50 (4%) 5/48 (10%) | 0/50 (0%) 1/50 (2%) 0/50 (0%) |
| Overall Incidence | Total | 8/148 (5.41%) | Mean 5.47% SD 4.4% | 0/50 (0%) 1/50 (2%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% |
| *Adrenal Cortex: Plasma Cell Tumor Malignant | | 0/50 (0%) | 0/50 (0%) 0/48 (0%) | 0/50 (0%) 1/50 (2%) 0/50 (0%) |
| Overall Incidence | Total | 0/30 (0%) | Mean 0% SD 0% | Total 1/150 (0.67%) Mean 0.67% SD 1.15% |
| *Adrenal Cortex: Sarcoma | | 0/50 (0%) | 0/50 (0%) 0/48 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (0%) |
| Overall Incidence | Total | 0/30 (0%) | Mean 0% SD 0% | Total 0/150 (0%) Mean 0% SD 0% |
| *Adrenal Medulla: Pheochromocytoma Benign | | (10) | | |
| Overall Incidence | Total | 0/49 (0%) 0/146 (0%) | 0/49 (0%) 0/48 (0%) Mean 0% SD 0% | 0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% |
| *Adrenal Medulla: Pheochromocytoma Complex | | 0/40 (00/) | 0/40 (00/) 0/40 (00/) | 0/50 (00/) 0/50 (00/) 0/50 (00/) |
| Overall Incidence | Total | 0/49 (0%) 0/146 (0%) | 0/49 (0%) 0/48 (0%) Mean 0% SD 0% | 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Species: MICE

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: B6C3F1 Vehicle: METHYLCELLULOSE Length of Study: CHRONIC

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| | | | Male | | | | Female | |
|---|---------------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| *Adrenal Medulla: Pheochromocytoma Mal | lignant | | | | | | | |
| Overall Incidence | Total | 0/49 (0%) 1/146 (0.68%) | 1/49 (2%) Mean 0.68% | 0/48 (0%) SD 1.18% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| *Adrenal Medulla: | | | | ••••• | | | ••••• | |
| Pheochromocytoma: Be | nign, Complex | 0/49 (0%) | 1/49 (2%) | 0/48 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 1/146 (0.68%) | Mean 0.68% | SD 1.18% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| *Bone Marrow: Hemangioma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| *Bone Marrow: Hemangiosarcoma | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 1/150 (0.67%) | Mean 0.67% | 0/50 (0%) SD 1.15% |
| *Bone Marrow: Plasma Cell Tumor Maliç | gnant | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| #Bone: Hemangiosarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date:04/29/2009

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | Female | |
|-----------------------------------|-------|-------------------------|--------------------------------------|---|-------|
| #Bone: Osteoma | | 0/50 (0%) | 1/50 (2%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% SD 1.15% | Total 0/150 (0%) Mean 0% SD 0% | |
| #Bone: Osteosarcoma | | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) 1/50 (2%) | ••••• |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% SD 0% | Total 2/150 (1.33%) Mean 1.33% SD 1.15% | |
| #Bone: Osteosarcoma or Osteoma | ı | 0/50 (0%) | 1/50 (2%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) 1/50 (2%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% SD 1.15% | Total 2/150 (1.33%) Mean 1.33% SD 1.15% | |
| #Bone: Sarcoma | | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (0%) | ••••• |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% SD 0% | Total 0/150 (0%) Mean 0% SD 0% | |
| *Brain: Meningioma Benign | | 0/50 (00/) | 0.50 (001) 0.50 (001) | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% | 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% | |
| *Brain: Meningioma Malignant | | 0/50 (004) | 0.50 (001) | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% | 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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| | | | Male | | | | Female | |
|--|-------------|-------------------------|----------------------|--------------------|-------|-------------------------|----------------------|--------------------|
| *Brain: Meningioma: Benign, Mal | ignant, NOS | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Brain: Schwannoma Malignant | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| *Clitoral/Preputial Gland: Adenoma | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/48 (0%) | 0/48 (0%) |
| Overall Incidence | Total | 0/149 (0%) | Mean 0% | SD 0% | Total | 0/143 (0%) | Mean 0% | SD 0% |
| *Clitoral/Preputial Gland: Carcinoma | | 0/50 (00/) | 0/40 (00/) | 0/50 (00/) | | 0/47 (00) | 0/40 (00/) | 0/40 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/49 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/47 (0%) 0/143 (0%) | 0/48 (0%) Mean 0% | 0/48 (0%) SD 0% |
| *Clitoral/Preputial Gland: Carcinoma or Adenoma | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/48 (0%) | 0/48 (0%) |
| Overall Incidence | Total | 0/149 (0%) | Mean 0% | SD 0% | Total | 0/143 (0%) | Mean 0% | SD 0% |
| *Clitoral/Preputial Gland: Hemangioma | | 0/50 (00/) | 0/40 /00/ | 0/50 (00/) | ••••• | 0.47 (00) | 0/40 (00/) | 0/40 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/49 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/47 (0%) 0/143 (0%) | 0/48 (0%) Mean 0% | 0/48 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|-------|-------------------------------|---------------------------|------------------------|-------|----------------------------|------------------------|-----------------------|
| *Clitoral/Preputial Gland: Hemangiosarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/49 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/47 (0%) 0/143 (0%) | 0/48 (0%) Mean 0% | 0/48 (0%) SD 0% |
| | | | | | | | | |
| Clitoral/Preputial Gland: Squamous Cell Carcinoma | | 0/50 (00/) | 0/40 (00/) | 0/50 (00/) | | 0/47 (00/) | 0/49 (00/) | 0/49 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/49 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/47 (0%) 0/143 (0%) | 0/48 (0%) Mean 0% | 0/48 (0%) SD 0% |
| | | | | | | | | |
| #Esophagus: Squamous Cell Carcinoma | | | | | | | -1 | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Overall incluence | TOtal | 0/130 (0%) | Mean 0% | 3D 0% | TOLAI | 0/150 (0%) | Weari 0% | 3D 0% |
| Eye: Sarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| overall incluence | Total | 0/130 (0%) | Mean 076 | 3D 0% | Total | 0/130 (0/8) | Weall 076 | 3D 0% |
| Harderian Gland: Adenoma | | | | | | | | |
| Overall Incidence | Total | 7/50 (14%) 23/150 (15.33%) | 8/50 (16%) Mean 15.33% | 8/50 (16%) SD 1.15% | Total | 9/50 (18%) 18/150 (12%) | 5/50 (10%) Mean 12% | 4/50 (8%) SD 5.29% |
| Jveran meluence | Total | 23/130 (13.33%) | WEATT 15.55% | 1.15% | Total | 10/100 (1270) | IVIEdII 1270 | SD 3.29% |
| Harderian Gland: Carcinoma | | | | | | | | |
| | | 2/50 (4%) | 2/50 (4%) | 3/50 (6%) | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 7/150 (4.67%) | Mean 4.67% | SD 1.15% | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|-------|----------------------------|-------------------------|-----------------------|-------|-------------------------|----------------------|--------------------|
| #Harderian Gland: Carcinoma or Adenoma | | 9/50 (18%) | 10/50 (20%) | 11/50 (22%) | | 10/50 (20%) | 6/50 (12%) | 4/50 (8%) |
| Overall Incidence | Total | 30/150 (20%) | Mean 20% | SD 2% | Total | 20/150 (13.33%) | Mean 13.33% | SD 6.11% |
| #Harderian Gland: Sarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/30 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Heart: Hemangioma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Heart: Hemangiosarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Heart: Sarcoma | | (201) | 2/52 (221) | | | (00) | (001) | (201) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Intestine Large: Cecum: Carcinoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|-------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| #Intestine Large: Cecum: Carcinoma or Adenoma | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Intestine Large: Cecum: Leiomyoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | ••••• | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Intestine Large: Colon/Rectum Leiomyosarcoma | | | | 0/50 (00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 /00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Intestine Small: Duodenum: Adenoma | | | | | | | 0/50 (0%) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | Mean 0% | 0/50 (0%) SD 0% |
| #Intestine Small: Duodenum: Carcinoma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% |
| #Intestine Small: Duodenum: Leiomyosarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | Female |
|--|-------|----------------------------|-----------------------------------|---|--------------------------------------|
| #Intestine Small: Duodenum: Polyp Adenomatous | | 0/50 (00/) | 0/50 (00) | (00) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 Mean 0% SD 0' | (0%) 0/50 (0%) 9% Total 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |
| #Intestine Small: Ileum: Carcinoma | ••••• | | | | 0/50 (00/) |
| Overall Incidence | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) 0/50 Mean 0.67% SD 1 | (0%) 0/50 (0%) .15% Total 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |
| #Intestine Small: Ileum: Hemangiosarcoma | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 Mean 0% SD 0' | (0%) 0/50 (0%) 9% Total 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |
| #Intestine Small: Ileum: Polyp Adenomatous | | 0/50 (0%) | 0/50 (0%) 0/50 | (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% SD 0 | ` , | Mean 0% SD 0% |
| #Intestine Small: Jejunum: Adenoma | ••••• | 0.70 | 272 (201) | | |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) 1/50 Mean 0.67% SD 1 | (2%) 0/50 (0%) .15% Total 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |
| #Intestine Small: Jejunum: Carcinoma | | | 2/22 (22) | | |
| Overall Incidence | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) 0/50 Mean 0.67% SD 1 | (0%) 0/50 (0%) .15% Total 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|-------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| #Intestine Small: Jejunum: Hemangiosarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Jejunum: Leiomyosarcoma | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Jejunum: Polyp Adenomatous | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Site Unspecif Adenoma | ied: | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Intestine Small: Site Unspecif Carcinoma | | | | | ••••• | | | |
| Overall Incidence | Total | 3/50 (6%) 3/150 (2%) | 0/50 (0%) Mean 2% | 0/50 (0%) SD 3.46% | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% |
| #Intestine Small: Site Unspecif Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 3/50 (6%) 4/150 (2.67%) | 0/50 (0%) Mean 2.67% | 1/50 (2%) SD 3.06% | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% |
| | | | | | | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|---|----------------------------|-------------------------|-----------------------|-------|---------------------------|-------------------------|-----------------------|
| #Intestine Small: Site Unspec Hemangiosarcoma | ified: | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Site Unspec Leiomyosarcoma | | | 4/50 (00) | 0/50 (00/) | ••••• | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Intestine Small: Site Unspec Polyp Adenomatous | ified: | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | ••••• | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/30 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Islets, Pancreatic: Adenoma | •••••• | 2/22 (191) | (22) | (201) | ••••• | | (201) | (201) |
| Overall Incidence | Total | 2/50 (4%) 6/150 (4%) | 4/50 (8%) Mean 4% | 0/50 (0%) SD 4% | Total | 0/49 (0%) 2/143 (1.4%) | 1/48 (2%) Mean 1.42% | 1/46 (2%) SD 1.23% |
| *Islets, Pancreatic: Carcinoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/49 (0%) 0/143 (0%) | 0/48 (0%) Mean 0% | 0/46 (0%) SD 0% |
| *Islets, Pancreatic: Carcinoma or Adenoma | • | 0/50 (40) | | 0/50 (004) | ••••• | 0/40 /00/ | | |
| Overall Incidence | Total | 2/50 (4%) 6/150 (4%) | 4/50 (8%) Mean 4% | 0/50 (0%) SD 4% | Total | 0/49 (0%) 2/143 (1.4%) | 1/48 (2%) Mean 1.42% | 1/46 (2%) SD 1.23% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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| | | | Male | | | | Female | |
|--|-------|----------------------------|---------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| *Kidney: Renal Tubule: Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/50 (0%) 0 Mean 0% | 0/49 (0%) SD 0% | Total | 0/50 (0%) 0/148 (0%) | 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% |
| Kidney: Renal Tubule: Carcinoma | | 0/50 (00/) | 0/50 (00) | (00/) | | 0/50 (00/) | 0/50 (00/) | 0/40 (00/) |
| Overall Incidence | Total | 0/50 (0%) 1/149 (0.67%) | 0/50 (0%) 1 Mean 0.68% | 1/49 (2%) SD 1.18% | Total | 0/50 (0%) 0/148 (0%) | 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% |
| Kidney: Renal Tubule: Carcinoma or Adenoma | | | (20) | (00) | | | | |
| Overall Incidence | Total | 0/50 (0%) 1/149 (0.67%) | 0/50 (0%) 1 Mean 0.68% | 1/49 (2%) SD 1.18% | Total | 0/50 (0%) 0/148 (0%) | 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% |
| Kidney: Renal Tubule: Hemangioma | | 0/50 (0%) | |)/49 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/48 (0%) |
| Overall Incidence | Total | 0/149 (0%) | 0/50 (0%) C Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| Kidney: Renal Tubule: Hemangiosarcoma | | 0/50 (00/) | 0/50 (00) | | ••••• | 0/50 (00/) | 0/50 (00/) | 0/40 (00%) |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/50 (0%) 0 Mean 0% | 0/49 (0%) SD 0% | Total | 0/50 (0%) 0/148 (0%) | 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% |
| Kidney: Renal Tubule: Plasma Cell Tumor Maligna | ınt | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/50 (0%) 0 Mean 0% | 0/49 (0%) SD 0% | Total | 0/50 (0%) 1/148 (0.68%) | 1/50 (2%) Mean 0.67% | 0/48 (0%) SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

or incidence for Selected Contr Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

| | | | Male | Female |
|-----------------------------------|-------|-----------------------------|--|--|
| *Liver: Cholangiocarcinoma | | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% SD 0% | Total 0/150 (0%) Mean 0% SD 0% |
| *Liver: Fibrous Histiocytoma | ••••• | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (0%) |
| Overall Incidence | Total | 0/30 (0%) | Mean 0% SD 0% | Total 0/150 (0%) Mean 0% SD 0% |
| *Liver: Hemangioma | | | | |
| Overall Incidence | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15% | 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% |
| *Liver: Hemangiosarcoma | | 2/50 (69/) | 2/50 /40/\ 2/50 /40/\ | 0/50 /09/\ 4/50 /09/\ 0/50 /09/\ |
| Overall Incidence | Total | 3/50 (6%) 7/150 (4.67%) | 2/50 (4%) 2/50 (4%) Mean 4.67% SD 1.15% | 0/50 (0%) 1/50 (2%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% |
| *Liver: Hepatoblastoma | | 2/52 (00/) | 0/50 /00/\ 0/50 /40/\ | 0/50 /00/) 0/50 /00/) |
| Overall Incidence | Total | 3/50 (6%) 8/150 (5.33%) | 3/50 (6%) 2/50 (4%) Mean 5.33% SD 1.15% | 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% |
| *Liver: Hepatocellular Adenoma | | | | |
| Overall Incidence | Total | 32/50 (64%) 84/150 (56%) | 24/50 (48%) 28/50 (56%) Mean 56% SD 8% | 14/50 (28%) 13/50 (26%) 15/50 (30%) Total 42/150 (28%) Mean 28% SD 2% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Male Female *Liver: **Hepatocellular Carcinoma** 26/50 (52%)(32%)13/50 (26%)(10%)3/50 (6%)(10%)16/50 **Overall Incidence** Total 55/150 (36.67%) Mean 36.67% SD 13.61% Total 13/150 (8.67%) Mean 8.67% SD 2.31% *Liver: Hepatocellular Carcinoma or Hepatoblastoma (54%)(30%)27/50 18/50 (36%)15/50 5/50 (10%)3/50 5/50 (10%)**Overall Incidence** 60/150 (40%) SD 12.49% (8.67%)SD 2.31% Total Mean 40% Total 13/150 Mean 8.67% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 33/50 (66%)37/50 (74%) 17/50 (34%)15/50 (30%)19/50 (38%) 41/50 (82%)Overall Incidence Total 111/150 (74%) Mean 74% SD 8% Total 51/150 (34%) Mean 34% SD 4% *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma (82%)33/50 (66%)38/50 17/50 (34%)15/50 (30%)19/50 (38%) 41/50 (76%)**Overall Incidence** Total 112/150 (74.67%) Mean 74.67% SD 8.08% Total 51/150 (34%) Mean 34% SD 4% *Liver: Hepatocholangiocarcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)SD 0% SD 0% Overall Incidence Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% *Liver: Hepatocholangioma 0/50 (0%)(2%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Report Date:04/29/2009

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| | | | Male | | | | Female | |
|---|--------------------|-------------------------------|---------------------------|-------------------------|-------|----------------------------|-------------------------|-----------------------|
| *Liver: Ito Cell Tumor Benign Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Liver: Ito Cell Tumor Malignant | | 0/50 (00/) | 0/50 (00/) | 0/50 /00/ | | 0/50 (00/) | 0/50 (00/) | 0/50 /00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| *Liver: Plasma Cell Tumor Maligna Overall Incidence | nt Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| 'Liver: Sarcoma Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| 'Lung: Adenoma Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| *Lung: Alveolar/Bronchiolar Adend | oma | 7/50 /4.49/ \ | 7/50 /4 49/ \ | 11/50 (229/) | | 0/50 (09/) | 3/50 (69/) | 1/50 (29/) |
| Overall Incidence | Total | 7/50 (14%) 25/150 (16.67%) | 7/50 (14%) Mean 16.67% | 11/50 (22%) SD 4.62% | Total | 0/50 (0%) 4/150 (2.67%) | 3/50 (6%) Mean 2.67% | 1/50 (2%) SD 3.06% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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| | | | Male | | | | Female | |
|---|-----------------|--------------------------------|----------------------------|-------------------------|-------|-----------------------------|-------------------------|------------------------|
| Lung: Alveolar/Bronchiolar Ca | arcinoma | 11/50 (22%) | 6/50 (12%) | 1/50 (2%) | | 4/50 (8%) | 1/50 (2%) | 5/50 (10%) |
| Overall Incidence | Total | 18/150 (12%) | Mean 12% | SD 10% | Total | 10/150 (6.67%) | Mean 6.67% | SD 4.16% |
| Lung: Alveolar/Bronchiolar Ca Adenoma | arcinoma or Alv | veolar/Bronchiolar | | | | | | |
| overall Incidence | Total | 16/50 (32%) 41/150 (27.33%) | 13/50 (26%) Mean 27.33% | 12/50 (24%) SD 4.16% | Total | 4/50 (8%) 14/150 (9.33%) | 4/50 (8%) Mean 9.33% | 6/50 (12%) SD 2.31% |
| ung: Fibrosarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| ung: Fibrous Histiocytoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| ung: Hemangiosarcoma | | 0/50 (00() | 0/50 (00/) | 0/50 (00/) | | 0/50 (00() | 0/50 (00) | 0/50 (00/) |
| overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| .ung: Plasma Cell Tumor Mali | ignant | 0/50 (00/) | 0/50 (00/) | 0(50 (004) | | 0/50 (004) | 4/50 (00) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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| | | | Male | | | | Female | |
|---|-------|-------------------------|----------------------|--------------------|-------|----------------------------|-------------------------|-----------------------|
| Lung: Sarcoma | | 0(50 (00)) | 0/50 (00/) | 0/50 (00/) | | 0(50 (00)) | 0/50 (00/) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Lymph Node: Fibrous Histiocytoma | | | | | | | | |
| · · · · · · · · · · · · · · · · · · · | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Lymph Node: Hemangioma | | | | | | | | |
| verall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| _ymph Node: | | | | | | | | |
| Hemangiosarcoma | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) |
| warell lead damag | Tatal | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Tatal | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Lymph Node: Plasma Cell Tumor Malign | ant | | | | | | | |
| i idollid ooli Tullioi Maligii | uiii | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |

......

0/50 (0%)

SD 0%

.....

0/50

Total

0/150 (0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

0/50

(0%)

Mean 0%

#Lymph Node: Sarcoma

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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| | | | Male | | | | Female | |
|---|-------|-------------------------|----------------------|--------------------|-------|----------------------------|-------------------------|-----------------------|
| Lymph Node, Bronchial: Hemangiosarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Lymph Node, Mandibular: Fibrous Histiocytoma | | 0/50 (00/) | 0/50 (0%) | 0/50 (00/) | | 0/50 (00/) | 0/50 /09/\ | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Lymph Node, Mandibular: Hemangiosarcoma | | | | | ••••• | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| _ymph Node, Mandibular: Mast Cell Tumor Malignant | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| ymph Node, Mandibular: Plasma Cell Tumor Malignant | | 0/50 (00/) | 0/50 (00/.) | 0/50 (00/) | | 0/50 (00) | 4/50 (00/) | 0/50 /00/ |
| overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| _ymph Node, Mesenteric: Fibrous Histiocytoma | | 0/50 (00/) | 0/50 (00/) | 0/50 (00) | ••••• | 0/50 (00) | 0/50 (00/) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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| | | Male | | | | Female | |
|-------|---------------------------------|--|---|---|--|---|--|
| | | | | | | | |
| | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | 0/50 (0%) |
| Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| ant | | | | | | | 0/50 (0%) |
| Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| | | | | | | | 0/50 (0%) |
| Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| | | | | | | | |
| Total | 0/50 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 4/150 (2.67%) | 1/50 (2%) Mean 2.67% | 2/50 (4%) SD 1.15% |
| | Total ant Total Total Total | Total 0/150 (0%) 0/50 (0%) Total 0/150 (0%) ant 0/50 (0%) Total 1/150 (0.67%) Total 0/150 (0%) Total 0/150 (0%) Total 0/150 (0%) | O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% ant O/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% | O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% SD 0% O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/50 (0%) 1/50 (2%) O/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total O/50 (0%) O/50 (0%) SD 0% Total O/150 (0%) O/50 (0%) O/50 (0%) Total O/150 (0%) O/50 (0%) O/50 (0%) Total O/150 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) | Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% Total ant | Total 0/50 (0%) 0/50 (0%) Nean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) ant 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 1/150 (0.67%) Total 0/150 (0%) 0/50 (0%) SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) | Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% ant 0/50 (0%) 1/50 (2%) 0/50 (0%) Total 0/150 (0%) 1/50 (0%) Mean 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 1/150 (0.67%) Mean 0.67% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0.67% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0.67% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|-----------------|-------------------------|----------------------|--------------------|-------|----------------------------|-------------------------|-----------------------|
| #Mammary Gland: Carcinoma or Adenoma | a | 0/50 (00/) | 0/50 /00/) | 0/50 (00/) | | 4/50 (00/) | 4/50 /00/ | 0/50 /40/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/50 (2%) 4/150 (2.67%) | 1/50 (2%) Mean 2.67% | 2/50 (4%) SD 1.15% |
| #Mammary Gland: Fibroadenoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/30 (0%) | Mean 0% | SD 0% |
| #Mammary Gland: Fibroma, Fibroadenoma | a or Adenoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Mammary Gland: Fibroma, Fibroadenoma | a, Carcinoma, o | | 0/50 (00/) | 0/50 (09/) | | 4/50 (20/) | 4/50 (20/) | 2/50 (40/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/50 (2%) 4/150 (2.67%) | 1/50 (2%) Mean 2.67% | 2/50 (4%) SD 1.15% |
| #Mesentery: Fibrosarcoma | | 0/50 (00/) | 0/50 (001) | 0/50 (001) | | 0/50 (004) | 0/50 (00/) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Mesentery: Hemangioma | | (004) | 2/22 (22) | (00) | | 0.000 | (201) | 2(72 (221) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|-----------------|----------------------|-----------|-----------|---|------------|-----------|-----------|
| Mesentery: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Mesentery: Sarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| lose: | | | | | • | | | |
| Mast Cell Tumor Malig | nant | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Oral Cavity (Oral Mucosa Papilloma Squamous o | , Tongue, Phary | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Oral Cavity (Oral Mucosa Squamous Cell Carcine | , Tongue, Phary | nx, Tooth, Gingiva): | ••••• | ••••• | | | ••••• | |
| _ | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma | , Tongue, Phary | | | | ••••• | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | Male | | Female | |
|---|-------|----------------------------|---------------------------|----------------------|
| *Ovary: Choriocarcinoma | | 0/40 (00/) | 4/40 (00/) | /47 (00/) |
| Overall Incidence | Total | 0/49 (0%) 1/144 (0.69%) | 1/48 (2%) 0 Mean 0.69% | /47 (0%) SD 1.2% |
| *Ovary: Cystadenoma | | (00) | (10) | (100) |
| Overall Incidence | Total | 4/49 (8%) 8/144 (5.56%) | 2/48 (4%) 2 Mean 5.53% | /47 (4%) SD 2.28% |
| *Ovary: Fibrous Histiocytoma | | 0/49 (0%) | 0/48 (0%) 0 | /47 (0%) |
| Overall Incidence | Total | 0/144 (0%) | Mean 0% | SD 0% |
| *Ovary: Granulosa Cell Tumor Benign | | 0/49 (0%) | 0/48 (0%) 0 | /47 (0%) |
| Overall Incidence | Total | 0/144 (0%) | Mean 0% | SD 0% |
| *Ovary: Granulosa Cell Tumor Malignant | | 0/49 (0%) | 0/48 (0%) 0 | /47 (0%) |
| Overall Incidence | Total | 0/144 (0%) | Mean 0% | SD 0% |
| *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS | | | | |
| Overall Incidence | Total | 0/49 (0%) 0/144 (0%) | 0/48 (0%) 0 Mean 0% | /47 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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| | Male | | | Female | |
|--|------|-------|----------------------------|-------------------------|-----------------------|
| *Ovary: Hemangioma | | | | | |
| Overall Incidence | | Total | 0/49 (0%) 0/144 (0%) | 0/48 (0%) Mean 0% | 0/47 (0%) SD 0% |
| *Ovary: | | | | | |
| Hemangiosarcoma Overall Incidence | | Total | 0/49 (0%) 1/144 (0.69%) | 0/48 (0%) Mean 0.71% | 1/47 (2%) SD 1.23% |
| *Ovary: Leiomyosarcoma | | | | | |
| Overall Incidence | | Total | 0/49 (0%) 0/144 (0%) | 0/48 (0%) Mean 0% | 0/47 (0%) SD 0% |
| *Ovary: | | | | | |
| Luteoma Overall Incidence | | Total | 0/49 (0%) 0/144 (0%) | 0/48 (0%) Mean 0% | 0/47 (0%) SD 0% |
| *Ovary: Plasma Cell Tumor Malignant | | | | | |
| Overall Incidence | | Total | 0/49 (0%) 1/144 (0.69%) | 1/48 (2%) Mean 0.69% | 0/47 (0%) SD 1.2% |
| *Ovary: Teratoma Benign | | | | | |
| Overall Incidence | | Total | 0/49 (0%) 0/144 (0%) | 0/48 (0%) Mean 0% | 0/47 (0%) SD 0% |
| | | | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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| | Male | | | | | Female | | | | |
|--|-------------|-------------------------|----------------------|--------------------|-------|----------------------------|-------------------------|-----------------------|--|--|
| *Ovary: Teratoma Malignant | | | | | | | | | | |
| Overall Incidence | | | | | Total | 0/49 (0%) 0/144 (0%) | 0/48 (0%) Mean 0% | 0/47 (0%) SD 0% | | |
| | | | | | | | | | | |
| *Ovary: Tubulostromal Adenoma | | | | | | 0/40 (00/) | 0/40 (00/) | 0/47 (00/) | | |
| Overall Incidence | | | | | Total | 0/49 (0%) 0/144 (0%) | 0/48 (0%) Mean 0% | 0/47 (0%) SD 0% | | |
| *Pancreas: Adenoma | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/48 (0%) | 0/46 (0%) | | |
| Overall Incidence | Total | 0/148 (0%) | Mean 0% | 0/48 (0%) SD 0% | Total | 0/49 (0%) | Mean 0% | 0/46 (0%) SD 0% | | |
| | | | | | | | | | | |
| *Pancreas: Carcinoma | | 0/50 (00/) | 0/50 (00/) | 0/40 (00/) | | 0/40 (00/) | 0/40 (00/) | 0/40 (00/) | | |
| Overall Incidence | Total | 0/50 (0%) 0/148 (0%) | 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% | Total | 0/49 (0%) 0/143 (0%) | 0/48 (0%) Mean 0% | 0/46 (0%) SD 0% | | |
| *Pancreas: Carcinoma or Adenoma | | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/148 (0%) | 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% | Total | 0/49 (0%) 0/143 (0%) | 0/48 (0%) Mean 0% | 0/46 (0%) SD 0% | | |
| ••••• | | | | | | | | | | |
| *Pituitary Gland: Pars Distalis Adenoma | or Unspecif | | 242 (224) | 2/22 (22/) | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/148 (0%) | 0/48 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/49 (2%) 4/144 (2.78%) | 2/49 (4%) Mean 2.77% | 1/46 (2%) SD 1.14% | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|-------------|------------|-----------|-----------|-------|---------------|------------|-----------|
| *Pituitary Gland: Pars Distalis Carcinoma | or Unspecif | ied Site: | | | | | | |
| | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | 0/46 (0%) |
| Overall Incidence | Total | 0/148 (0%) | Mean 0% | SD 0% | Total | 0/144 (0%) | Mean 0% | SD 0% |
| *Pituitary Gland: Pars Distalis Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) | | 1/49 (2%) | 2/49 (4%) | 1/46 (2%) |
| Overall Incidence | Total | 0/148 (0%) | Mean 0% | SD 0% | Total | 4/144 (2.78%) | Mean 2.77% | SD 1.14% |
| *Pituitary Gland: Pars Interme Adenoma | edia: | | | | | | | |
| | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | 1/46 (2%) |
| Overall Incidence | Total | 0/148 (0%) | Mean 0% | SD 0% | Total | 1/144 (0.69%) | Mean 0.72% | SD 1.26% |
| *Pituitary Gland: Pars Interme Carcinoma or Adenoma | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | 1/46 (2%) |
| Overall Incidence | Total | 0/148 (0%) | Mean 0% | SD 0% | Total | 1/144 (0.69%) | Mean 0.72% | SD 1.26% |
| | | | | | | | | |
| *Prostate: Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) | | | | |
| Overall Incidence | Total | 0/148 (0%) | Mean 0% | SD 0% | | | | |
| *Prostate: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) | | | | |
| Overall Incidence | Total | 0/148 (0%) | Mean 0% | SD 0% | | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|-------|-------------------------|----------------------|--------------------|-------|----------------------------|-------------------------|-----------------------|
| *Prostate: Hemangioma | | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) | | | | |
| Overall Incidence | Total | 0/148 (0%) | Mean 0% | SD 0% | | | | |
| *Salivary Glands: Carcinoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/43 (0%) | Mean 0% | SD 0% |
| *Salivary Glands: Carcinoma or Adenoma | | (504) | 2(20) | 0.000 | | (201) | | 2/22 (221) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/49 (0%) 0/148 (0%) | 0/49 (0%) Mean 0% | 0/50 (0%) SD 0% |
| *Salivary Glands: Mast Cell Tumor Malignant | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/148 (0%) | Mean 0% | SD 0% |
| #Seminal Vesicle: Adenoma | | 0/50 (00() | 0(50 (00)) | 0/50 (00/) | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | | | | |
| #Skeletal Muscle: Fibrosarcoma | | 0/50 (00() | 0/50 (00/) | 0/50 (00) | | 4/50 (000) | 0/50 (00) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|------------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| #Skeletal Muscle: Hemangiosarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 2/150 (1.33%) | 2/50 (4%) Mean 1.33% | 0/50 (0%) SD 2.31% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Skeletal Muscle: Myxosarcoma | | 0.700 (001) | 0.70 | (201) | | (70) | (201) | 0/20 (00) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| #Skeletal Muscle: Rhabdomyosarcoma | | | | | ••••• | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| #Skeletal Muscle: Rhabdomyosarcoma or R | thabdomyom | | 0/50 (00/) | 0/50 (09/) | | 0/50 (/0//) | 4/50 (20() | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| #Skeletal Muscle: Sarcoma | | | | | ••••• | | | |
| Overall Incidence | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Skin: Basal Cell Adenoma or B | asosquamou | • | | | ••••• | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | | | Female | | | | |
|---|---------------------------------|-------------------------|----------------------|--------------------|--------|----------------------------|-------------------------|-----------------------|--|--|
| #Skin: Basal Cell Adenoma, E Trichoepithelioma | Basosquamous ' | Tumor Benign, or | | | | | | | | |
| • | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% | | |
| #Skin: Basal Cell Carcinoma | | 0/50 (0%) | | | ••••• | 0/50 (0%) | | 1/50 /29/\ | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% | | |
| #Skin: Basal Cell Carcinoma (NOS) | or Basosquamo | us Tumor (malignant or | | | •••••• | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% | | |
| #Skin: Basal Cell Carcinoma, Tumor (benign, malign | | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | | |
| #Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan | noma, Carcinor oma, Adenoma, | Papilloma, Sq | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | | |
| #Skin: Basosquamous Tumo | r Benign | 0/50 (00() | 0/50 (00/) | 0/50 (0%) | | 0/50 (00/) | 0/50 (00/) | 0/50 /00/ | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | | |

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| 0/50 (0%) 0/150 (0%) oma, M yxosarcoma, or | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
|---|---|---|--|--|---|---|
| 0/150 (0%) | ` , | ` ' | Total | ` ' | ` ' | ` ' |
| oma. Myxosarcoma. or | | | | | | |
| z, myxoodi ooiild, oi | | | | | | |
| 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | Total | 5/50 (10%) | 3/50 (6%) | 3/50 (6%) SD 2.31% |
| ` , | | | | ` , | | |
| | | | | | | 3/50 (6%) |
| 0/150 (0%) | Mean 0% | SD 0% | Total | 8/150 (5.33%) | Mean 5.33% | SD 1.15% |
| ı, or Fibrous 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | | 5/50 (10%) | 3/50 (6%) | 3/50 (6%) |
| 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total | 11/150 (7.33%) | Mean 7.33% | SD 2.31% |
| 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | 2/150 (1.33%) 0/50 (0%) 0/150 (0%) 1, or Fibrous 1/50 (2%) 2/150 (1.33%) | 2/150 (1.33%) Mean 1.33% 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% 1, or Fibrous 1/50 (2%) 0/50 (0%) 2/150 (1.33%) Mean 1.33% 1/50 (2%) 0/50 (0%) 1/150 (0.67%) Mean 0.67% | 2/150 (1.33%) Mean 1.33% SD 1.15% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% SD 0% 1, or Fibrous 1/50 (2%) 0/50 (0%) 1/50 (2%) 2/150 (1.33%) Mean 1.33% SD 1.15% 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/150 (0.67%) Mean 0.67% SD 1.15% | 2/150 (1.33%) Mean 1.33% SD 1.15% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% SD 0% Total 1, or Fibrous 1/50 (2%) 0/50 (0%) 1/50 (2%) 2/150 (1.33%) Mean 1.33% SD 1.15% Total 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/150 (0.67%) Mean 0.67% SD 1.15% Total | 2/150 (1.33%) Mean 1.33% SD 1.15% Total 11/150 (7.33%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 3/50 (6%) 0/150 (0%) Mean 0% SD 0% Total 8/150 (5.33%) 1, or Fibrous 1/50 (2%) 0/50 (0%) 1/50 (2%) 2/150 (1.33%) Mean 1.33% SD 1.15% Total 11/150 (7.33%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) | 2/150 (1.33%) Mean 1.33% SD 1.15% Total 11/150 (7.33%) Mean 7.33% 0/50 (0%) 0/50 (0%) 0/50 (0%) 3/50 (6%) 2/50 (4%) 0/150 (0%) Mean 0% SD 0% Total 8/150 (5.33%) Mean 5.33% 1, or Fibrous 1/50 (2%) 0/50 (0%) 1/50 (2%) 5/50 (10%) 3/50 (6%) 2/150 (1.33%) Mean 1.33% SD 1.15% Total 11/150 (7.33%) Mean 7.33% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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| | | | Male | | | | Female | |
|--|----------------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| ‡Skin: Hemangioma | | 0/50 (00/) | 0/50 (00/) | 0/50 (09/) | | 0/50 (0%) | 0/50 (0%) | 4/50 (20() |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% |
| ≄Skin: Hemangiosarcoma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% | 1/50 (2%) SD 1.15% | Total | 1/50 (2%) 3/150 (2%) | 1/50 (2%) Mean 2% | 1/50 (2%) SD 0% |
| Skin: Liposarcoma | ••••• | 0/50 (0%) | 0/50 (09/) | 0/50 (0%) | | 0/50 (0%) | 0/50 (09/) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Skin: Myxosarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| Skin: Neurofibrosarcoma or S | | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| Skin: Neurofibrosarcoma, Nei malignant or NOS) | urofibroma, or | , , | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|---------------------------------------|-------------------------|----------------------|-----------------------|-------|-------------------------|----------------------|-----------------------|
| #Skin: Osteosarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Skin: Sarcoma | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | 1/50 (2%) SD 1.15% | Total | 2/150 (1.33%) | Mean 1.33% | 0/50 (0%) SD 1.15% |
| #Skin: Schwannoma Malignant | •••• | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| #Skin: Squamous Cell Carcinom | a | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Skin: Squamous Cell Carcinom Basosquamous Tumor (n | | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| #Skin: Squamous Cell Papilloma | · · · · · · · · · · · · · · · · · · · | 0/50 (004) | 0/50 (00/) | 0/50 (00) | | 0/50 /00/ | 0/50 (00/) | 0/50 (00) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | Female | | | | Male | | | | | | | | | | |
|--|------------|------------------|--------|------|-------|-------|--------|-------|-------|-------|------|--------|-------|---------|-----------------|-----------------------|
| Solid Control Contro | (0%) | 0/50 // | (0%) | 0/50 | (0%) | 0/50 | | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | oma | loma or Papille | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) | ` ' | SD 0% | ` , | | ` , | | Total | ` , | | ` ' | | ` , | | I | Total | Overall Incidence |
| Description Total O/150 (0%) Mean 0% SD 0% Total O/150 (0%) Mean 0% SD 0% | | | | | ••••• | | | ••••• | ••••• | ••••• | | s Cell | amous | na, Squ | | Squamous Cell Papil |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 0/50 (0%) 0/5 | (0%) 0% | 0/50 (0 SD 0% | ` , | | ` , | | Total | ` , | | ` ' | | ` , | | I | Total | Overall Incidence |
| #Skin: Trichoepithelioma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) Mean 0% #Skin: Sebaceous Gland: Adenoma 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) Overall Incidence Total 0/150 (0%) Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) O/50 (0%) O | (0%) | , | ` , | | ` ' | | Turk | ` , | | ` , | | (0%) | 0/50 | • | • | Squamous Cell Papil |
| Trichoepithelioma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Nean 0% SD (0%) SD (0%) Nean 0% SD (0%) Nean 0% SD (0%) 0/50 (0%) | 0% | SD 0% | ∌an 0% | Mea | (0%) | 0/150 | l otal | 0% | SD | า 0% | Mear | (0%) |)/150 | ! | l otal | Overall Incidence |
| Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Skin: Sebaceous Gland: Adenoma 0/50 (0%) 0/50 | (0%) | 0/50 ((| (0%) | 0/50 | (0%) | 0/50 | | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | | | _ |
| #Skin: Sebaceous Gland: Adenoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% | ` ' | SD 0% | ` , | | ` , | | Total | ` , | | ` ' | | ` , | | I | Total | Overall Incidence |
| Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0 | | | | | | | | | | | | | | | | Skin: Sebaceous Gland |
| | (0%) 0% | 0/50 (C SD 0% | ` , | | ` ' | | Total | ` , | | ` ' | | ` ' | | I | Total | Overall Incidence |
| Carcinoma | | | | | | | | | | | | | | ••••• | | Skin: Sebaceous Gland |
| 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% | (0%) 0% | 0/50 (0 SD 0% | ` , | | ` , | | Total | ` , | | ` ' | | ` ' | | I | Total | Overall Incidence |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date:04/29/2009

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|-------|----------------------------|-------------------------|----------------------|-------|----------------------------|-------------------------|-----------------------|
| #Skin: Sebaceous Gland: Carcinoma or Adenoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Spinal Cord: Meningioma Malignant | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Spleen: Fibrous Histiocytoma | | 0/50 (00/) | 0/50 (001) | 0(10 (00)) | ••••• | 0/50 (00) | 0/50 (00/) | 0/47 (00) |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/50 (0%) Mean 0% | 0/49 (0%) SD 0% | Total | 0/50 (0%) 0/147 (0%) | 0/50 (0%) Mean 0% | 0/47 (0%) SD 0% |
| *Spleen: Hemangioma | | 0/50 (00/) | 0/50 (00/) | 0/40 (00/) | | 0/50 (00/) | 0/50 (0%) | 0/47 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/50 (0%) Mean 0% | 0/49 (0%) SD 0% | Total | 0/50 (0%) 0/147 (0%) | 0/50 (0%) Mean 0% | 0/47 (0%) SD 0% |
| *Spleen: Hemangiosarcoma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) 4/149 (2.68%) | 1/50 (2%) Mean 2.69% | 2/49 (4%) SD 1.2% | Total | 0/50 (0%) 1/147 (0.68%) | 1/50 (2%) Mean 0.67% | 0/47 (0%) SD 1.15% |
| *Spleen: Mast Cell Tumor Malignant | t | | | | ••••• | | | |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/50 (0%) Mean 0% | 0/49 (0%) SD 0% | Total | 0/50 (0%) 0/147 (0%) | 0/50 (0%) Mean 0% | 0/47 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|--------|-------------------------|----------------------|--------------------|--------|-------------------------|----------------------|--------------------|
| Spleen: Plasma Cell Tumor Malignan | t | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/47 (0%) |
| Overall Incidence | Total | 0/149 (0%) | Mean 0% | SD 0% | Total | 1/147 (0.68%) | Mean 0.67% | SD 1.15% |
| Stomach, Forestomach: Mast Cell Tumor Malignant | | 0/50 (00/) | 0/50 (0%) | 0/50 (00/) | | 0/50 (00/) | 0/50 (0%) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| verali ilicidence | I Olai | 0/130 (0/8) | Mean 076 | 30 0% | ı Olai | 0/130 (0/8) | Weall 076 | 30 0% |
| Stomach, Forestomach: Squamous Cell Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Stomach, Forestomach: Squamous Cell Carcinoma o | | | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| Stomach, Forestomach: Squamous Cell Papilloma | | | | | | | | |
| oquamous com rapinoma | | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| Stomach, Glandular: Adenoma | | 0/50 (00/) | 0/50 (00) | 0/50 (00() | | 0/50 /00/ | 0/50 (0%) | 0/50 (0%) |
| | T-1-1 | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | T-1-1 | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | Female |
|--|-------|----------------------------|--|----------------------------------|--------------------------------------|
| #Stomach, Glandular: Carcinoma | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 (0° Mean 0% SD 0% | %) 0/50 (0%) Total 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |
| #Stomach, Glandular: Carcinoma or Adenoma | | 0/50 (0%) | 0/50 (0%) 0/50 (04 | %) 0/50 (0%) | 0/50 (0%) 0/50 (0%) |
| Overall Incidence | Total | 0/30 (0%) | Mean 0% SD 0% | , | Mean 0% SD 0% |
| *Testes: Adenoma | | 0/50 (00/) | 4/52 (00) | | |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) 0/50 (0° Mean 0.67% SD 1.15 | | |
| Testes: Hemangiosarcoma | | 0/50 (0%) | 0/50 (0%) 0/50 (04 | 0/ \ | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 (0° Mean 0% SD 0% | 70) | |
| Thymus: Thymoma Benign | | 0/45 (00/) | | 2/47 (20) | 2/12 (22) |
| Overall Incidence | Total | 0/45 (0%) 0/127 (0%) | 0/44 (0%) 0/38 (0° Mean 0% SD 0% | , | 0/46 (0%) 0/43 (0%) Mean 0% SD 0% |
| *Thymus: Thymoma Malignant | | 0/45 (09/) | 0/44 (00/) 0/29 (0 | 0/\ 0/47 /00/\ | 0/46 (09/) 0/42 (09/) |
| Overall Incidence | Total | 0/45 (0%) 0/127 (0%) | 0/44 (0%) 0/38 (0° Mean 0% SD 0% | %) 0/47 (0%) Total 0/136 (0%) | 0/46 (0%) 0/43 (0%) Mean 0% SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|---------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| *Thymus: Thymoma: Benign, Malignan | nt, NOS | 0/45 (00/) | 0/44 (00/) | 0/29 (00/) | | 0/47 (00/) | 0/46 (00/) | 0/42 (00/) |
| Overall Incidence | Total | 0/45 (0%) 0/127 (0%) | 0/44 (0%) Mean 0% | 0/38 (0%) SD 0% | Total | 0/47 (0%) 0/136 (0%) | 0/46 (0%) Mean 0% | 0/43 (0%) SD 0% |
| *Thyroid Gland: Adenoma | | 0/50 (00/) | 0/40 (00/) | 0/50 (00/) | | 0/50 (00() | 0/50 (0%) | 0/40 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/49 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/146 (0%) | 0/50 (0%) Mean 0% | 0/46 (0%) SD 0% |
| *Thyroid Gland: C-Cell: Carcinoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/149 (0%) | 0/49 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/146 (0%) | 0/50 (0%) Mean 0% | 0/46 (0%) SD 0% |
| *Thyroid Gland: C-Cell: Carcinoma or Adenoma | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/46 (0%) |
| Overall Incidence | Total | 0/149 (0%) | Mean 0% | SD 0% | Total | 0/36 (0%) | Mean 0% | SD 0% |
| *Thyroid Gland: Follicular Cell: Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 4/149 (2.68%) | 1/49 (2%) Mean 2.68% | 3/50 (6%) SD 3.05% | Total | 1/50 (2%) 2/146 (1.37%) | 0/50 (0%) Mean 1.39% | 1/46 (2%) SD 1.21% |
| *Thyroid Gland: Follicular Cell: Carcinoma | | 0/50 (00/) | | 0/50 (00) | | 4/50 (000) | | 0/40 (00/) |
| Overall Incidence | Total | 0/50 (0%) 1/149 (0.67%) | 1/49 (2%) Mean 0.68% | 0/50 (0%) SD 1.18% | Total | 1/50 (2%) 1/146 (0.68%) | 0/50 (0%) Mean 0.67% | 0/46 (0%) SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | Female | | |
|---|-------|----------------------------|--|---|------|--|
| *Thyroid Gland: Follicular Cell Carcinoma or Adenoma | : | 0/50 (0%) | 2/49 (4%) 3/50 (6%) | 2/50 (4%) 0/50 (0%) 1/46 (3 | 2%) | |
| Overall Incidence | Total | 5/149 (3.36%) | Mean 3.36% SD 3.06% | Total 3/146 (2.05%) Mean 2.06% SD 2% | , | |
| #Tissue NOS: Carcinoma | ••••• | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (| 0%) | |
| Overall Incidence | Total | 0/30 (0%) | Mean 0% SD 0% | Total 0/150 (0%) Mean 0% SD 0% | , | |
| #Tissue NOS: Hemangiosarcoma | ••••• | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (| 0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% SD 0% | Total 0/150 (0%) Mean 0% SD 0% | , | |
| #Tissue NOS: Plasma Cell Tumor Maligna | ant | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) 0/50 (| 0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% SD 0% | Total 1/150 (0.67%) Mean 0.67% SD 1.1 | , | |
| #Tissue NOS: Schwannoma Malignant | | 0/50 (09/) | 0/50 (09/) 0/50 (09/) | 0/50 (0%) 0/50 (0%) 0/50 (| 00() | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% | 0/50 (0%) 0/50 (0%) 0/50 (0 Total 0/150 (0%) Mean 0% SD 0% | 0%) | |
| #Tongue: Fibroma | | 0/50 (004) | 4/50 (00) | 0/50 (00) 0/50 (00) | 004) | |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15% | 0/50 (0%) 0/50 (0%) 0/50 (0 Total 0/150 (0%) Mean 0% SD 0% | 0%) | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | | | | Female | |
|--------------------------------------|-------------|-------------------------|----------------------|--------------------|-------|-------------------------|----------------------|--------------------|
| #Tongue: Squamous Cell Carcinoma | | 0/50 (00/) | 0/50 (00/) | 0/50 /00/ | | 0/50 /00/ | 0/50 (00/) | 0/50 (09/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Tongue: | | | | ••••• | | | | |
| Squamous Cell Carcinoma | or Papillon | | 0/50 (00/) | 0/50 (00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) |
| Overall Institutes | T-4-1 | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Tatal | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Tongue: Squamous Cell Papilloma | | | 2/52 (221) | - () | | 2/22 (221) | (201) | 2/52 (201) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Tooth: Odontoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Urinary Bladder: Hemangioma | | | | | | | | |
| - | | 0/50 (0%) | 0/50 (0%) | 0/48 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/45 (0%) |
| Overall Incidence | Total | 0/148 (0%) | Mean 0% | SD 0% | Total | 0/145 (0%) | Mean 0% | SD 0% |
| *Urinary Bladder: Hemangiosarcoma | | 0/50 (09/) | 0/50 (0%) | 1/49 (20/) | | 0/50 (09/) | 0/50 (09/) | 0/45 (09/) |
| Overell Insidence | T-4-1 | 0/50 (0%) | 0/50 (0%) | 1/48 (2%) | Tatal | 0/50 (0%) | 0/50 (0%) | 0/45 (0%) |
| Overall Incidence | Total | 1/148 (0.68%) | Mean 0.69% | SD 1.2% | Total | 0/145 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|--------|-------------------------|----------------------|--------------------|-------|----------------------------|-------------------------|-----------------------|
| *Urinary Bladder: Plasma Cell Tumor Mali | ignant | 0/50 (00/) | 0/50 (09/) | 0/49 (09/) | | 0/50 (00/) | 1/50 /20/ | 0/45 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/148 (0%) | 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% | Total | 0/50 (0%) 1/145 (0.69%) | 1/50 (2%) Mean 0.67% | 0/45 (0%) SD 1.15% |
| *Urinary Bladder: Sarcoma | | 0/50 (00/) | 0/50 (0%) | 0/49 /09/\ | | 0/50 (09/) | 0/50 (00/) | 0/45 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/148 (0%) | 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% | Total | 0/50 (0%) 0/145 (0%) | 0/50 (0%) Mean 0% | 0/45 (0%) SD 0% |
| #Uterus: Adenoma | | | | | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% |
| #Uterus: Carcinoma | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | | | | | Total | 0/30 (0%) | Mean 0% | SD 0% |
| #Uterus: Hemangioma | | ••••• | ••••• | ••••• | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Uterus: Hemangiosarcoma | | | | | ••••• | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

| | Male | | | Female | |
|--|------|-------|-------------------------|----------------------|--------------------|
| #Uterus: Leiomyoma | | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| #Uterus: Leiomyosarcoma | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Uterus: Polyp Stromal Overall Incidence | | Total | 2/50 (4%) | 1/50 (2%) | 0/50 (0%) |
| Overall incidence | | Total | 3/150 (2%) | Mean 2% | SD 2% |
| #Uterus: Sarcoma Stromal | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Uterus: Sarcoma Stromal or Polyp Stromal | | | 2/50 (4%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | | Total | 3/150 (2%) | Mean 2% | SD 2% |
| #Uterus: Schwannoma Malignant | | | 0/50 /00/ | 0/50 (00/) | 0/50 /09/ |
| Overall Incidence | | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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| | | | Male | | Female | | | |
|--|-------|-------------------------|----------------------|--------------------|--------|-------------------------|----------------------|--------------------|
| #Vagina: Squamous Cell Carcinoma | | | | | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | | | | | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| #Vagina: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | | | | | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Zymbal's Gland: Carcinoma | | 0/50 (00/) | 0/50 (00/) | 0(50 (00)) | | 0/50 (00/) | 0/50 (00/) | 0/50 (001) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Zymbal's Gland: Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied