

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: WATER

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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 |
|------------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|------------------------------|
| Male | | | | | | | |
| Battelle Columbus Laboratory | 058812305 | 03/21/01 | 727 | 50(3) | 26(673) | 509.7 | Formamide |
| Battelle Columbus Laboratory | 052000505 | 01/21/04 | 727 | 50(3) | 30(679) | 498.5 | Ginseng |
| Battelle Columbus Laboratory | 059501107 | 03/06/02 | 727 | 50(3) | 22(673) | 510.3 | 5-(Hydroxymethyl)-2-furfural |
| Female | | | | | | | |
| Battelle Columbus Laboratory | 058812305 | 03/20/01 | 730 | 50(5) | 38(703) | 358.3 | Formamide |
| Battelle Columbus Laboratory | 052000505 | 01/22/04 | 728 | 50(5) | 36(700) | 355.0 | Ginseng |
| Battelle Columbus Laboratory | 059501107 | 03/07/02 | 728 | 50(5) | 31(679) | 332.2 | 5-(Hydroxymethyl)-2-furfural |

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| | | Male | | | Female | | |
|--------------------------------------|-------|-----------------|-------------|--------------|------------------------|-------------|-------------|
| #All Organs: | | | | | | | |
| Benign Tumors | | | | | | | |
| | | 45/50 (90%) | 49/50 (98%) | 50/50 (100%) | 43/50 (86%) | 42/50 (84%) | 46/50 (92%) |
| Overall Incidence | Total | 144/150 (96%) | Mean 96% | SD 5.29% | Total 131/150 (87.33%) | Mean 87.33% | SD 4.16% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Tumors | | | | | | | |
| | | 25/50 (50%) | 26/50 (52%) | 35/50 (70%) | 15/50 (30%) | 10/50 (20%) | 16/50 (32%) |
| Overall Incidence | Total | 86/150 (57.33%) | Mean 57.33% | SD 11.02% | Total 41/150 (27.33%) | Mean 27.33% | SD 6.43% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant and Benign Tumors | | | | | | | |
| | | 48/50 (96%) | 49/50 (98%) | 50/50 (100%) | 49/50 (98%) | 45/50 (90%) | 48/50 (96%) |
| Overall Incidence | Total | 147/150 (98%) | Mean 98% | SD 2% | Total 142/150 (94.67%) | Mean 94.67% | SD 4.16% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| 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% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| 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% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma or 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% |

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

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| | | Male | | | Female | | | |
|--|-------|-----------------|-------------|-------------|-------------|-----------------|-------------|----------|
| #All Organs: | | | | | | | | |
| Histiocytic Sarcoma | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 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% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Leukemia: Erythrocytic | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated | | | | | | | | |
| | | 15/50 (30%) | 18/50 (36%) | 28/50 (56%) | 10/50 (20%) | 6/50 (12%) | 9/50 (18%) | |
| Overall Incidence | Total | 61/150 (40.67%) | Mean 40.67% | SD 13.61% | Total | 25/150 (16.67%) | Mean 16.67% | SD 4.16% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | |
| | | 2/50 (4%) | 2/50 (4%) | 2/50 (4%) | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 6/150 (4%) | Mean 4% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |

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

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| | | Male | | | Female | | | |
|--------------------------------|-------|---------------|------------|-----------|-----------|---------------|------------|----------|
| #All Organs: | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | |
| | | 2/50 (4%) | 2/50 (4%) | 2/50 (4%) | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 6/150 (4%) | Mean 4% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteoma | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteosarcoma | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 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% | SD 1.15% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 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% | SD 1.15% |
| | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 (0%) | 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% |
| | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | | Male | | | | Female | | | |
|--|-------|--------------|-----------|------------|-------|---------------|------------|-----------|--|
| *Adrenal Medulla: Ganglioneuroma | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | |
| *Adrenal Medulla: 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% | |
| | | | | | | | | | |
| *Adrenal Medulla: Pheochromocytoma Benign | | | | | | | | | |
| | | 9/50 (18%) | 4/50 (8%) | 5/50 (10%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 18/150 (12%) | Mean 12% | SD 5.29% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | |
| | | | | | | | | | |
| *Adrenal Medulla: Pheochromocytoma Complex | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | |
| *Adrenal Medulla: Pheochromocytoma 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% | |
| | | | | | | | | | |
| *Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | | |
| | | 9/50 (18%) | 4/50 (8%) | 5/50 (10%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 18/150 (12%) | Mean 12% | SD 5.29% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | | Male | | | | Female | | | |
|------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|-----------|
| #Bone: | | | | | | | | | |
| Chondrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 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% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Chondrosarcoma or Chondroma | | | | | | | | | |
| | | 0/50 (0%) | 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% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Chordoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 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: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 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% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | | Male | | | | Female | | | | | |
|-----------------------------------|-------|-------|------|---------|-------|--------|-------|---------|------------|----------|------|
| *Brain: | | | | | | | | | | | |
| Astrocytoma Malignant | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Ependymoma Benign | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Ependymoma Malignant | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Glioma Malignant | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| *Brain: | | | | | | | | | | | |
| Medulloblastoma Mal | | | | | | | | | | | |
| | | 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% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | | Male | | | | Female | | | | | | | |
|--|-------|-------|------|---------|----------|--------|-------|------|---------|-------|------|------|------|
| *Brain: | | | | | | | | | | | | | |
| Oligodendroglioma Benign | | | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | | | |
| Oligodendroglioma Malignant | | | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | | | |
| Osteosarcoma | | | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | | | | | |
| | | 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% | | | |
| | | | | | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 5/50 | (10%) | 2/50 | (4%) | 1/50 | (2%) | 3/50 | (6%) |
| Overall Incidence | Total | 6/150 | (4%) | Mean 4% | SD 5.29% | Total | 6/150 | (4%) | Mean 4% | SD 2% | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | | Male | | | Female | | | |
|--|-------|---------------|------------|------------|-----------|---------------|------------|----------|
| *Clitoral/Preputial Gland: Carcinoma | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| *Clitoral/Preputial Gland: Carcinoma or Adenoma | | | | | | | | |
| | | 2/50 (4%) | 0/50 (0%) | 6/50 (12%) | 2/50 (4%) | 2/50 (4%) | 3/50 (6%) | |
| Overall Incidence | Total | 8/150 (5.33%) | Mean 5.33% | SD 6.11% | Total | 7/150 (4.67%) | Mean 4.67% | SD 1.15% |
| | | | | | | | | |
| *Clitoral/Preputial Gland: Fibrosarcoma | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| *Clitoral/Preputial Gland: 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% |
| | | | | | | | | |
| #Ear: Neural Crest Tumor | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| #Esophagus: Fibrosarcoma | | | | | | | | |
| | | 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% |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | | |
|-----------------------------|-------|---------------|------------|-----------|-----------|---------------|------------|----------|
| #Esophagus: | | | | | | | | |
| Lipoma | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| #Eye: | | | | | | | | |
| Melanoma 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% |
| | | | | | | | | |
| #Eye: | | | | | | | | |
| Schwannoma 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% |
| | | | | | | | | |
| #Harderian Gland: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| #Harderian Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| *Heart: | | | | | | | | |
| Schwannoma Benign | | | | | | | | |
| | | 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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | |
|--|-------|------------|-----------|-----------|-----------|---------------|------------------------|
| *Heart: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | 0/50 (0%) | 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% |
| | | | | | | | |
| #Intestine Large: Colon/Rectum: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | 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% |
| | | | | | | | |
| #Intestine Large: Colon/Rectum: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 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: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | 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% |
| | | | | | | | |
| #Intestine Large: Colon/Rectum: | | | | | | | |
| 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% |
| | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | |
|--------------------------------------|-------|---------------|------------|-----------|-----------|---------------|------------------------|
| #Intestine Small: Duodenum: | | | | | | | |
| Leiomyoma | | | | | | | |
| | | 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% |
| | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | |
| 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% |
| | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 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: | | | | | | | |
| Granular Cell Tumor 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% |
| | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | |
| 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 Small: Jejunum: | | | | | | | |
| Leiomyosarcoma | | | | | | | |
| | | 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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | Female | | |
|--|-------|---------------|------------|-----------|-----------|---------------|------------------------|
| #Intestine Small: Site Unspecified: 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% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma | | | | | | | |
| | | 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: Site Unspecified: Carcinoma or Adenoma | | | | | | | |
| | | 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: Site Unspecified: Granular Cell Tumor 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% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyoma | | | | | | | |
| | | 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% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyosarcoma | | | | | | | |
| | | 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% |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | | |
|--|-------|---------------|------------|-----------|-----------|---------------|------------|----------|
| *Islets, Pancreatic: Adenoma | | | | | | | | |
| | | 2/50 (4%) | 0/50 (0%) | 2/50 (4%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 4/150 (2.67%) | Mean 2.67% | SD 2.31% | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% |
| | | | | | | | | |
| *Islets, Pancreatic: Carcinoma | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 3/150 (2%) | Mean 2% | SD 2% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Islets, Pancreatic: Carcinoma or Adenoma | | | | | | | | |
| | | 3/50 (6%) | 0/50 (0%) | 4/50 (8%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 7/150 (4.67%) | Mean 4.67% | SD 4.16% | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% |
| | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: Carcinoma | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: 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% |
| | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: Papilloma | | | | | | | | |
| | | 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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | |
|--|-------|---------------|------------|-----------|-----------|------------|------------------|
| *Kidney: Renal Tubule: Adenoma | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: Carcinoma | | | | | | | |
| | | 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% |
| | | | | | | | |
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | |
| | | 1/50 (2%) | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 3/150 (2%) | Mean 2% | SD 2% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: 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% |
| | | | | | | | |
| *Kidney: Renal Tubule: Lipoma | | | | | | | |
| | | 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% |
| | | | | | | | |
| *Kidney: Renal Tubule: Mesenchymal Tumor Benign | | | | | | | |
| | | 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% |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | | |
|------------------------------------|-------|------------|-----------|-----------|-----------|---------------|------------|----------|
| *Kidney: Renal Tubule: | | | | | | | | |
| Mesenchymal Tumor Malignant | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | |
| Nephroblastoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Total | 0/50 (0%) | 0/50 (0%) | |
| | | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | |
| Sarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Total | 0/50 (0%) | 0/50 (0%) | |
| | | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Cholangioma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Total | 0/50 (0%) | 0/50 (0%) | |
| | | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Total | 0/50 (0%) | 0/50 (0%) | |
| | | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Total | 2/50 (4%) | 0/50 (0%) | |
| | | 0/150 (0%) | Mean 0% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | | |
|--|-------|---------------|------------|-----------|-----------|---------------|------------|----------|
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Ito Cell Tumor Benign | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | 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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | | Female | | | | | |
|---|-------|---------------|------|------------|------|----------|------|-------|------|---------------|------|
| *Lung: | | | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 2/150 (1.33%) | | Mean 1.33% | | SD 1.15% | | Total | | 1/150 (0.67%) | |
| | | | | Mean 0.67% | | | | | | SD 1.15% | |
| | | | | | | | | | | | |
| *Lung: | | | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 1/50 | (2%) | 2/50 | (4%) | 1/50 | (2%) |
| Overall Incidence | Total | 2/150 (1.33%) | | Mean 1.33% | | SD 1.15% | | Total | | 3/150 (2%) | |
| | | | | Mean 2% | | | | | | SD 2% | |
| | | | | | | | | | | | |
| *Lung: | | | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| *Lung: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| *Lung: | | | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| #Lymph Node: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 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% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 114
 Report Date: 03/20/2010

| | | Male | | | | Female | | | |
|---|-------|---------------|------------|-----------|-------|-----------------|-------------|-------------|--|
| #Mammary Gland: Adenolipoma | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | |
| #Mammary Gland: Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 2/50 (4%) | 2/50 (4%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 4/150 (2.67%) | Mean 2.67% | SD 2.31% | |
| | | | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% | |
| | | | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 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% | |
| | | | | | | | | | |
| #Mammary Gland: Fibroadenoma | | | | | | | | | |
| | | 2/50 (4%) | 2/50 (4%) | 1/50 (2%) | | 33/50 (66%) | 32/50 (64%) | 29/50 (58%) | |
| Overall Incidence | Total | 5/150 (3.33%) | Mean 3.33% | SD 1.15% | Total | 94/150 (62.67%) | Mean 62.67% | SD 4.16% | |
| | | | | | | | | | |
| #Mammary Gland: Fibroma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 115
 Report Date: 03/20/2010

| | | Male | | | Female | | |
|---|-------|---------------|------------|-----------|--------|-----------------|-------------|
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | |
| | | 4/50 (8%) | 2/50 (4%) | 1/50 (2%) | | 33/50 (66%) | 33/50 (66%) |
| Overall Incidence | Total | 7/150 (4.67%) | Mean 4.67% | SD 3.06% | Total | 96/150 (64%) | Mean 64% |
| | | | | | | 30/50 (60%) | SD 3.46% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | |
| | | 4/50 (8%) | 2/50 (4%) | 1/50 (2%) | | 35/50 (70%) | 33/50 (66%) |
| Overall Incidence | Total | 7/150 (4.67%) | Mean 4.67% | SD 3.06% | Total | 98/150 (65.33%) | Mean 65.33% |
| | | | | | | 30/50 (60%) | SD 5.03% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Fibrous Histiocytoma | | | | | | | |
| | | 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% |
| | | | | | | 0/50 (0%) | SD 0% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 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% |
| | | | | | | 0/50 (0%) | SD 0% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Lipoma | | | | | | | |
| | | 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% |
| | | | | | | 0/50 (0%) | SD 0% |
| | | | | | | | |
| #Mesentery: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | 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% |
| | | | | | | 0/50 (0%) | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 116
 Report Date: 03/20/2010

| | | Male | | | | Female | | | | | | | |
|---|-------|-------|------|---------|-------|--------|-------|---------|------------|----------|------|------|------|
| *Nose: | | | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | | | |
| | | 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% | | | |
| | | | | | | | | | | | | | |
| *Nose: | | | | | | | | | | | | | |
| Chondroma | | | | | | | | | | | | | |
| | | 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% | | | |
| | | | | | | | | | | | | | |
| *Nose: | | | | | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | | | | | |
| | | 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% | | | |
| | | | | | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | | | | | |
| Papilloma Squamous or Papilloma | | | | | | | | | | | | | |
| | | 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% | | | |
| | | | | | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | | | | | |
| | | 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% | | | |
| | | | | | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | | | | | | |
| | | 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% | | | |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | | Female | | | |
|---|-------|------------|-----------|-----------|-------|---------------|------------|-----------|--|
| #Oral Mucosa: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | |
| #Oral Mucosa: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | |
| *Ovary: | | | | | | | | | |
| Cystadenoma | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | |
| Overall Incidence | | | | | Total | 0/149 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Ovary: | | | | | | | | | |
| Granulosa Cell Tumor Benign | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | |
| Overall Incidence | | | | | Total | 0/149 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Ovary: | | | | | | | | | |
| Granulosa Cell Tumor Malignant | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | |
| Overall Incidence | | | | | Total | 0/149 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Ovary: | | | | | | | | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | |
| Overall Incidence | | | | | Total | 0/149 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 118
 Report Date: 03/20/2010

| Male | | | | | Female | | | | | | |
|--|--|-------|-------|---------|------------|----------|-------|---------|-------|---------|-------|
| *Ovary: | | | | | | | | | | | |
| Granulosa-Theca Tumor Benign | | | | | | | | | | | |
| | | | | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | |
| Overall Incidence | | | | | Total | 0/149 | (0%) | Mean 0% | SD 0% | | |
| | | | | | | | | | | | |
| *Ovary: | | | | | | | | | | | |
| Granulosa-Theca Tumor Malignant | | | | | | | | | | | |
| | | | | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | |
| Overall Incidence | | | | | Total | 0/149 | (0%) | Mean 0% | SD 0% | | |
| | | | | | | | | | | | |
| *Ovary: | | | | | | | | | | | |
| Tubulostromal Adenoma | | | | | | | | | | | |
| | | | | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | |
| Overall Incidence | | | | | Total | 0/149 | (0%) | Mean 0% | SD 0% | | |
| | | | | | | | | | | | |
| *Pancreas: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | | | 0/50 | (0%) |
| Overall Incidence | | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | | |
| *Pancreas: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 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% |
| | | | | | | | | | | | |
| *Pancreas: | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | | | 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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 119
 Report Date: 03/20/2010

| | | Male | | | | Female | | | |
|---|-------|--------|----------|-------------|----------|--------|--------|----------|-------------|
| *Pancreas: | | | | | | | | | |
| Mixed Tumor Benign | | | | | | | | | |
| | | 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% |
| | | | | | | | | | |
| *Pancreas: | | | | | | | | | |
| Mixed Tumor Malignant | | | | | | | | | |
| | | 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% |
| | | | | | | | | | |
| *Parathyroid Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/48 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/46 | (0%) |
| Overall Incidence | Total | 0/147 | (0%) | Mean 0% | SD 0% | Total | 0/142 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 11/50 | (22%) | 20/50 | (40%) | 15/50 | (30%) | 22/50 | (44%) |
| Overall Incidence | Total | 46/150 | (30.67%) | Mean 30.67% | SD 9.02% | Total | 62/150 | (41.33%) | Mean 41.33% |
| | | | | | | | | | SD 8.33% |
| | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 2/50 | (4%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 3/150 | (2%) | Mean 2% |
| | | | | | | | | | SD 2% |
| | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 11/50 | (22%) | 20/50 | (40%) | 15/50 | (30%) | 24/50 | (48%) |
| Overall Incidence | Total | 46/150 | (30.67%) | Mean 30.67% | SD 9.02% | Total | 65/150 | (43.33%) | Mean 43.33% |
| | | | | | | | | | SD 9.87% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 120
 Report Date: 03/20/2010

| | | Male | | | | Female | | | | | |
|---|-------|-------|---------|------------|----------|--------|-------|------|---------|-------|------|
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | | | |
| Ganglioneuroma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| *Pituitary Gland: Pars Nervosa: | | | | | | | | | | | |
| Craniopharyngioma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| *Prostate: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | | | | | | |
| | | | | | | | | | | | |
| *Prostate: | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | | | | | | |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 121
 Report Date: 03/20/2010

| | | Male | | | | Female | | | | | |
|-------------------------------|-------|-------|---------|------------|----------|--------|-------|------|---------|-------|------|
| *Salivary Glands: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | | | |
| Sarcoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | | | | | | |
| | | | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | | | |
| | | 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% | |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | | Female | | | | | |
|--|-------|-------|------|---------|-------|--------|-------|---------|------------|----------|------|
| #Skeletal Muscle: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | | | |
| Rhabdomyosarcoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | | | | | |
| | | 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 Adenoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | 1/50 | (2%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 3/150 | (2%) | Mean 2% | SD 0% | Total | 2/150 | (1.33%) | Mean 1.33% | SD 1.15% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Basal Cell Adenoma or Basosquamous Tumor Benign | | | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | 1/50 | (2%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 3/150 | (2%) | Mean 2% | SD 0% | Total | 2/150 | (1.33%) | Mean 1.33% | SD 1.15% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma | | | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | 1/50 | (2%) | 2/50 | (4%) | 1/50 | (2%) |
| Overall Incidence | Total | 3/150 | (2%) | Mean 2% | SD 0% | Total | 3/150 | (2%) | Mean 2% | SD 2% | |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | | |
|---|-------|-----------------|-------------|------------|-----------|---------------|------------|----------|
| #Skin: | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | |
| | | 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 or Basosquamous Tumor (malignant or NOS) | | | | | | | | |
| | | 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, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | 2/50 (4%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 3/150 (2%) | Mean 2% | SD 0% | Total | 3/150 (2%) | Mean 2% | SD 2% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | |
| | | 10/50 (20%) | 2/50 (4%) | 4/50 (8%) | 4/50 (8%) | 3/50 (6%) | 0/50 (0%) | |
| Overall Incidence | Total | 16/150 (10.67%) | Mean 10.67% | SD 8.33% | Total | 7/150 (4.67%) | Mean 4.67% | SD 4.16% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibroma | | | | | | | | |
| | | 6/50 (12%) | 2/50 (4%) | 5/50 (10%) | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 13/150 (8.67%) | Mean 8.67% | SD 4.16% | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 7/50 (14%) | 3/50 (6%) | 6/50 (12%) | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 16/150 (10.67%) | Mean 10.67% | SD 4.16% | 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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | |
|--|-------|----------------|------------|-----------|-----------|---------------|------------------------|
| #Skin: | | | | | | | |
| Fibrosarcoma | | | | | | | |
| | | 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% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 3/150 (2%) | Mean 2% | SD 0% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Fibrous Histiocytoma | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| 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% |
| | | | | | | | |
| #Skin: | | | | | | | |
| 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% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Keratoacanthoma | | | | | | | |
| | | 8/50 (16%) | 0/50 (0%) | 2/50 (4%) | 2/50 (4%) | 2/50 (4%) | 0/50 (0%) |
| Overall Incidence | Total | 10/150 (6.67%) | Mean 6.67% | SD 8.33% | Total | 4/150 (2.67%) | Mean 2.67% SD 2.31% |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | | Female | | | | | |
|---|-------|-------|---------|------------|----------|--------|-------|---------|------------|----------|------|
| #Skin: | | | | | | | | | | | |
| Lipoma | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Liposarcoma | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Neural Crest Tumor | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Neural Crest Tumor, Malignant | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Neurofibroma or Schwannoma benign | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 2/150 | (1.33%) | Mean 1.33% | SD 1.15% | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 126
 Report Date: 03/20/2010

| | | Male | | | | Female | | | | | | | | | |
|---|-------|---------------|------|------------|------|----------|------|-------|------|---------------|------|------------|------|----------|--|
| #Skin: | | | | | | | | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | | |
| Overall Incidence | Total | 2/150 (1.33%) | | Mean 1.33% | | SD 1.15% | | Total | | 1/150 (0.67%) | | Mean 0.67% | | SD 1.15% | |
| | | | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | | | |
| 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% | |
| | | | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | | | |
| Schwannoma Benign | | | | | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | | |
| Overall Incidence | Total | 2/150 (1.33%) | | Mean 1.33% | | SD 1.15% | | Total | | 1/150 (0.67%) | | Mean 0.67% | | SD 1.15% | |
| | | | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | | |
| Overall Incidence | Total | 2/150 (1.33%) | | Mean 1.33% | | SD 1.15% | | Total | | 0/150 (0%) | | Mean 0% | | SD 0% | |
| | | | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | | |
| Overall Incidence | Total | 2/150 (1.33%) | | Mean 1.33% | | 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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 127
 Report Date: 03/20/2010

| | | Male | | | | Female | | | | | | | |
|---|-------|----------------|-------|------------|------|----------|------|-------|---------------|------|------------|------|----------|
| #Skin: | | | | | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | | Mean 0.67% | | SD 1.15% | | Total | 1/150 (0.67%) | | Mean 0.67% | | SD 1.15% |
| | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | | Mean 0.67% | | SD 1.15% | | Total | 1/150 (0.67%) | | Mean 0.67% | | SD 1.15% |
| | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | | | | | | |
| | | 9/50 | (18%) | 1/50 | (2%) | 3/50 | (6%) | 2/50 | (4%) | 3/50 | (6%) | 0/50 | (0%) |
| Overall Incidence | Total | 13/150 (8.67%) | | Mean 8.67% | | SD 8.33% | | Total | 5/150 (3.33%) | | Mean 3.33% | | SD 3.06% |
| | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | | | | | | |
| | | 9/50 | (18%) | 0/50 | (0%) | 2/50 | (4%) | 2/50 | (4%) | 3/50 | (6%) | 0/50 | (0%) |
| Overall Incidence | Total | 11/150 (7.33%) | | Mean 7.33% | | SD 9.45% | | Total | 5/150 (3.33%) | | Mean 3.33% | | SD 3.06% |
| | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | |
| Trichoepithelioma | | | | | | | | | | | | | |
| | | 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: Sebaceous Gland: | | | | | | | | | | | | | |
| 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% |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 128
 Report Date: 03/20/2010

| | | Male | | | | Female | | | | | |
|--------------------------------|-------|-------|------|---------|-------|--------|-------|---------|------------|----------|------|
| #Skin: Sebaceous Gland: | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Astrocytoma Benign | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Astrocytoma Malignant | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Glioma Malignant | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| *Spleen: | | | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | | | |
| | | 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 | (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% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: WATER

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| | | Male | | | | Female | | | | | |
|--|-------|-------|---------|------------|----------|--------|-------|---------|------------|----------|------|
| *Spleen: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 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: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 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% | |
| | | | | | | | | | | | |
| *Spleen: | | | | | | | | | | | |
| Sarcoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | | | |
| | | 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% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | | |
|--------------------------------|-------|------------------|-------------|-------------|-----------|------------|-----------|-------|
| #Stomach, Forestomach: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | |
| 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% |
| | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | |
| Lipoma | | | | | | | | |
| | | 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% |
| | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | |
| 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% |
| | | | | | | | | |
| *Testes: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 44/50 (88%) | 45/50 (90%) | 48/50 (96%) | | | | |
| Overall Incidence | Total | 137/150 (91.33%) | Mean 91.33% | SD 4.16% | | | | |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | |
|--|-------|--------------|-------------|-----------|------------|-----------------|-------------------------|
| *Testes: | | | | | | | |
| Hemangioma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma Benign | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) | 1/48 (2%) |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 1/144 (0.69%) | Mean 0.69% SD 1.2% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma Malignant | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/48 (0%) | 0/48 (0%) | 1/48 (2%) | 0/48 (0%) |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 1/144 (0.69%) | Mean 0.69% SD 1.2% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma NOS | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 0/144 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/48 (0%) | 0/48 (0%) | 1/48 (2%) | 1/48 (2%) |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 2/144 (1.39%) | Mean 1.39% SD 1.2% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Adenoma | | | | | | | |
| | | 6/50 (12%) | 11/50 (22%) | 1/50 (2%) | 5/50 (10%) | 6/50 (12%) | 11/50 (22%) |
| Overall Incidence | Total | 18/150 (12%) | Mean 12% | SD 10% | Total | 22/150 (14.67%) | Mean 14.67% SD 6.43% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | | |
|--|-------|---------------|-------------|-----------|------------|-----------------|-------------|----------|
| *Thyroid Gland: C-Cell: Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 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% |
| | | | | | | | | |
| *Thyroid Gland: C-Cell: Carcinoma or Adenoma | | | | | | | | |
| | | 6/50 (12%) | 11/50 (22%) | 1/50 (2%) | 5/50 (10%) | 6/50 (12%) | 12/50 (24%) | |
| Overall Incidence | Total | 18/150 (12%) | Mean 12% | SD 10% | Total | 23/150 (15.33%) | Mean 15.33% | SD 7.57% |
| | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 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% | SD 1.15% |
| | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | |
| Overall Incidence | Total | 4/150 (2.67%) | Mean 2.67% | SD 1.15% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |
| | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 3/50 (6%) | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | |
| Overall Incidence | Total | 5/150 (3.33%) | Mean 3.33% | SD 2.31% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |
| | | | | | | | | |
| #Tissue NOS: Lipoma | | | | | | | | |
| | | 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% |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | |
|--|-------|------------|-----------|-----------|-----------|------------|------------------|
| #Tissue NOS: | | | | | | | |
| Paraganglioma | | | | | | | |
| | | 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% |
| | | | | | | | |
| #Tongue: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 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% |
| | | | | | | | |
| #Tongue: | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | |
| | | 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% |
| | | | | | | | |
| #Tongue: | | | | | | | |
| Squamous Cell Papilloma | | | | | | | |
| | | 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: | | | | | | | |
| Adamantinoma 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% |
| | | | | | | | |
| #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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | | Female | | | | | |
|---|-------|-------|------|---------|-------|--------|-------|------|---------|-------|------|
| *Urinary Bladder: Carcinoma or Papilloma | | | | | | | | | | | |
| | | 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: Hemangiosarcoma | | | | | | | | | | | |
| | | 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: Leiomyosarcoma | | | | | | | | | | | |
| | | 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: Papilloma | | | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | | | |
| #Uterus: Adenoma | | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | | | | | | Total | 0/150 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Uterus: Carcinoma | | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | | | | | | Total | 0/150 | (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 135
 Report Date: 03/20/2010

| | Male | Female |
|-------------------------------------|-------------------------------------|---------------------------------------|
| #Uterus: Deciduoma Benign | | |
| Overall Incidence | Total 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% SD 0% |
| #Uterus: Hemangioma | | |
| Overall Incidence | Total 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% SD 0% |
| #Uterus: Hemangiosarcoma | | |
| Overall Incidence | Total 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% SD 0% |
| #Uterus: Leiomyosarcoma | | |
| Overall Incidence | Total 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% SD 0% |
| #Uterus: Polyp Stromal | | |
| Overall Incidence | Total 7/50 (14%) 23/150 (15.33%) | 8/50 (16%) Mean 15.33% SD 1.15% |
| #Uterus: Sarcoma | | |
| Overall Incidence | Total 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | | | Male | | | | | Female |
|---|--|-----------|------------|------------|-----------------|-------------|------------|------------|------------|
| #Uterus: | | | | | | | | | |
| Sarcoma Stromal | | | | | | | | | |
| | | | | 0/50 (0%) | | | | | 0/50 (0%) |
| Overall Incidence | | | | Total | 0/150 (0%) | Mean 0% | | 0/50 (0%) | SD 0% |
| | | | | | | | | | |
| #Uterus: | | | | | | | | | |
| Sarcoma Stromal or Polyp Stromal | | | | | | | | | |
| | | | | 7/50 (14%) | | | | | 8/50 (16%) |
| Overall Incidence | | | | Total | 23/150 (15.33%) | Mean 15.33% | | 8/50 (16%) | SD 1.15% |
| | | | | | | | | | |
| #Uterus: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | | | 1/50 (2%) | | | | | 0/50 (0%) |
| Overall Incidence | | | | Total | 1/150 (0.67%) | Mean 0.67% | | 0/50 (0%) | SD 1.15% |
| | | | | | | | | | |
| #Vagina: | | | | | | | | | |
| Polyp | | | | | | | | | |
| | | | | 0/50 (0%) | | | | | 0/50 (0%) |
| Overall Incidence | | | | Total | 0/150 (0%) | Mean 0% | | 0/50 (0%) | SD 0% |
| | | | | | | | | | |
| #Vagina: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | | | 0/50 (0%) | | | | | 0/50 (0%) |
| Overall Incidence | | | | Total | 0/150 (0%) | Mean 0% | | 0/50 (0%) | SD 0% |
| | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 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% |

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

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 03/20/2010

| | | Male | | | Female | | |
|-----------------------------|-------|------------|-----------|-----------|-----------|------------|---------------|
| #Zymbal's Gland: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 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% |
| | | | | | | | |
| #Zymbal's 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% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied