

B-12

Talc, NTP TR 421

TABLE B2 Individual Animal Tumor Pathology of Female Rats in the Lifetime Inhalation Study of Talc: 6 mg/m³

Table with columns for Number of Days on Study (4-8), Carcass ID Number (0-10), and various Organ Systems (Alimentary, Cardiovascular, Endocrine) with tumor findings (+, A, M, X).

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Board Draft

Lesions in Female Rats

B-13

TABLE B2
Individual Animal Tumor Pathology of Female Rats in the Lifetime Inhalation Study of Talc: 6 mg/m³ (continued)

| Number of Days on Study | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 | | | | | | | | | | | | | | | | | | | | Total Tissues/ Tumors |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| | 8 9 9 9 0 1 1 1 1 4 4 6 6 6 6 6 6 6 6 6 6 | | | | | | | | | | | | | | | | | | | | |
| Carcass ID Number | 6 8 8 9 0 2 5 8 9 1 9 2 2 2 2 2 2 2 3 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | |
| | 1 0 1 1 0 0 0 0 1 0 0 0 0 0 0 0 0 0 1 1 1 1 | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | 4 2 4 3 8 1 3 6 1 4 6 1 1 2 2 4 6 7 8 9 1 3 3 4 |
| | | | | | | | | | | | | | | | | | | | | | 4 4 3 8 5 4 7 6 7 4 4 6 8 0 1 7 2 1 6 1 1 3 6 0 |
| | | | | | | | | | | | | | | | | | | | | | 1 |
| Alimentary System | | | | | | | | | | | | | | | | | | | | | |
| Esophagus | + | | | | | | | | | | | | | | | | | | | | 48 |
| Intestine large | + | | | | | | | | | | | | | | | | | | | | 43 |
| Intestine large, cecum | A A A A + + + + + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | 34 |
| Intestine large, colon | + A + | | | | | | | | | | | | | | | | | | | | 41 |
| Intestine large, rectum | + M + + + + + + + M + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | 37 |
| Intestine small | + | | | | | | | | | | | | | | | | | | | | 46 |
| Intestine small, duodenum | + + + + + + + + M + + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | 44 |
| Intestine small, ileum | A A A A + A + + + + + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | 32 |
| Intestine small, jejunum | + A + | | | | | | | | | | | | | | | | | | | | 40 |
| Liver | + | | | | | | | | | | | | | | | | | | | | 48 |
| Hepatocellular carcinoma | | | | | | | | | | | | | | | | | | | | | X |
| Neoplastic nodule | X X | | | | | | | | | | | | | | | | | | | | 3 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | 2 |
| Pancreas | + M + | | | | | | | | | | | | | | | | | | | | 46 |
| Salivary glands | + | | | | | | | | | | | | | | | | | | | | 48 |
| Lymphoma malignant lymphocytic, metastatic | X | | | | | | | | | | | | | | | | | | | | 1 |
| Sarcoma | | | | | | | | | | | | | | | | | | | | | 1 |
| Stomach | + | | | | | | | | | | | | | | | | | | | | 47 |
| Stomach, forestomach | + + + + + + + + + + + + + + M + M + + + + + + + + | | | | | | | | | | | | | | | | | | | | 45 |
| Stomach, glandular | + | | | | | | | | | | | | | | | | | | | | 47 |
| Tongue | + | | | | | | | | | | | | | | | | | | | | 2 |
| Sarcoma, metastatic | | | | | | | | | | | | | | | | | | | | | 1 |
| Squamous cell papilloma | X | | | | | | | | | | | | | | | | | | | | 1 |
| Tooth | | | | | | | | | | | | | | | | | | | | | 1 |
| Adamantinoma benign | | | | | | | | | | | | | | | | | | | | | 1 |
| Cardiovascular System | | | | | | | | | | | | | | | | | | | | | |
| Blood vessel | + | | | | | | | | | | | | | | | | | | | | 3 |
| Heart | + | | | | | | | | | | | | | | | | | | | | 48 |
| Endocrine System | | | | | | | | | | | | | | | | | | | | | |
| Adrenal gland | + | | | | | | | | | | | | | | | | | | | | 47 |
| Adrenal gland, cortex | + | | | | | | | | | | | | | | | | | | | | 47 |
| Adrenal gland, medulla | + | | | | | | | | | | | | | | | | | | | | 47 |
| Pheochromocytoma malignant | X | | | | | | | | | | | | | | | | | | | | 1 |
| Pheochromocytoma benign | X X X X X X X X X X | | | | | | | | | | | | | | | | | | | | 10 |
| Bilateral, pheochromocytoma benign | X | | | | | | | | | | | | | | | | | | | | 4 |
| Islets, pancreatic | + M + | | | | | | | | | | | | | | | | | | | | 45 |
| Adenoma | | | | | | | | | | | | | | | | | | | | | X |
| Parathyroid gland | + M M I + | | | | | | | | | | | | | | | | | | | | 42 |
| Pituitary gland | + | | | | | | | | | | | | | | | | | | | | 47 |
| Pars distalis, adenoma | X | | | | | | | | | | | | | | | | | | | | 18 |
| Pars distalis, carcinoma | X | | | | | | | | | | | | | | | | | | | | 3 |
| Thyroid gland | + | | | | | | | | | | | | | | | | | | | | 47 |
| C-cell, carcinoma | X X | | | | | | | | | | | | | | | | | | | | 2 |
| Follicular cell, adenoma | X | | | | | | | | | | | | | | | | | | | | 1 |

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TABLE B2
Individual Animal Tumor Pathology of Female Rats in the Lifetime Inhalation Study of Talc: 6 mg/m³ (continued)

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Number of Days on Study | 4 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 8 | 0 | 2 | 5 | 6 | 6 | 6 | 4 | 5 | 6 | 7 | 9 | 9 | 0 | 2 | 2 | 2 | 3 | 4 | 4 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | |
| | 2 | 8 | 6 | 7 | 1 | 6 | 6 | 7 | 1 | 8 | 8 | 0 | 7 | 5 | 0 | 4 | 9 | 8 | 0 | 7 | 5 | 0 | 2 | 6 | 8 | | | |
| Carcass ID Number | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 3 | 4 | 6 | 3 | 6 | 4 | 9 | 1 | 9 | 4 | 1 | 4 | 9 | 7 | 4 | 0 | 1 | 8 | 1 | 3 | 1 | 6 | 2 | 1 | 6 | | | |
| | 8 | 8 | 8 | 7 | 9 | 3 | 5 | 0 | 6 | 1 | 8 | 5 | 2 | 0 | 0 | 9 | 6 | 9 | 5 | 9 | 2 | 7 | 3 | 7 | 3 | | | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| General Body System | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| None | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Genital System | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clitoral gland | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ovary | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Granulosa cell tumor benign | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Granulosa-theca tumor benign | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Lymphoma malignant lymphocytic, metastatic | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Polyp stromal | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sarcoma stromal | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic System | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bone marrow | + | A | + | + | + | + | A | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Lymph node | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Lymph node, bronchial | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + |
| Lymph node, mandibular | + | A | + | M | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Sarcoma, metastatic | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph node, mediastinal | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Lymph node, mesenteric | + | A | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Spleen | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Thymus | + | A | + | + | + | + | + | + | + | + | + | + | M | M | + | + | + | + | I | + | + | + | + | + | + | + | + | |
| Mixed tumor malignant | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Myxoma | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Integumentary System | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + |
| Adenoma | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fibroadenoma | X | | | | | | X | | | | | | | | | | | | | | | | | | | | | |
| Fibroma | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymphoma malignant lymphocytic, metastatic | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Keratoacanthoma | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Subcutaneous tissue, fibrosarcoma | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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TABLE B2
Individual Animal Tumor Pathology of Female Rats in the Lifetime Inhalation Study of Talc: 6 mg/m³ (continued)

| | |
|--|---|
| Number of Days on Study | 4 5 5 5 5 5 6 6 6 6 6 6 7 7 7 7 7 7 7 7 7 |
| | 8 0 2 5 6 6 6 4 5 6 7 9 9 0 2 2 2 3 4 4 5 6 6 6 6 |
| | 2 8 6 7 1 6 6 7 1 8 8 0 7 5 0 4 9 8 0 7 5 0 2 6 8 |
| Carcass ID Number | 0 0 0 1 0 0 0 1 0 1 1 0 0 0 0 1 1 0 1 0 1 0 0 0 0 |
| | 3 4 6 3 6 4 9 1 9 4 1 4 9 7 4 0 1 8 1 3 1 6 2 1 6 |
| | 8 8 8 7 9 3 5 0 6 1 8 5 2 0 0 9 6 9 5 9 2 7 3 7 3 |
| | 1 |
| Musculoskeletal System | |
| Bone | + A + |
| Mandible, sarcoma, metastatic | X |
| Skeletal muscle | |
| Liposarcoma | |
| Nervous System | |
| Brain | + A + |
| Carcinoma, metastatic, pituitary gland | X |
| Respiratory System | |
| Larynx | + A + |
| Lung | + A + |
| Nose | + A + + + + + A + + + + + + + + + A + + + A + + + + |
| Trachea | + A + |
| Special Senses System | |
| Harderian gland | + + |
| Urinary System | |
| Kidney | + A + + + + + A + + + + + + + + + + + + + + + + |
| Lipoma | |
| Lymphoma malignant lymphocytic, metastatic | |
| Urinary bladder | + A + M + + + A + + + + + + + + + + + + + + + + |
| Systemic Lesions | |
| Multiple organs | + |
| Leukemia mononuclear | X X X X X X X X X X X |
| Lymphoma malignant lymphocytic | X |
| Lymphoma malignant mixed | X |

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Lesions in Female Rats

B-17

TABLE B2
Individual Animal Tumor Pathology of Female Rats in the Lifetime Inhalation Study of Talc: 6 mg/m³ (continued)

| | | |
|--|---|--------------------------------------|
| Number of Days on Study | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 | |
| | 8 9 9 9 0 1 1 1 1 4 4 6 6 6 6 6 6 6 6 6 6 6 | |
| | 6 8 8 9 0 2 5 8 9 1 9 2 2 2 2 2 2 2 3 3 3 3 | |
| Carcass ID Number | 1 0 1 1 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 1 1 1 1 | Total Tissues/ Tumors |
| | 4 2 4 3 8 1 3 6 1 4 6 1 1 2 2 4 6 7 8 9 1 3 3 4 | |
| | 4 4 3 8 5 4 7 6 7 4 4 6 8 0 1 7 2 1 6 1 1 3 6 0 | |
| | 1 | |
| Musculoskeletal System | | |
| Bone | + | 48 |
| Mandible, sarcoma, metastatic | | 1 |
| Skeletal muscle | | 1 |
| Liposarcoma | | X |
| Nervous System | | |
| Brain | + + + + + + + + - + + + + + + + + + + + + + + + | 48 |
| Carcinoma, metastatic, pituitary gland | | 1 |
| Respiratory System | | |
| Larynx | + | 48 |
| Lung | + | 48 |
| Nose | + | 45 |
| Trachea | + | 48 |
| Special Senses System | | |
| Harderian gland | + | 7 |
| Urinary System | | |
| Kidney | + | 47 |
| Lipoma | | X |
| Lymphoma malignant lymphocytic, metastatic | X | 1 |
| Urinary bladder | + M + | 45 |
| Systemic Lesions | | |
| Multiple organs | + | 49 |
| Leukemia mononuclear | X | 20 |
| Lymphoma malignant lymphocytic | X | 2 |
| Lymphoma malignant mixed | | X X X X X X X X |
| | | 1 |

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B-18

Talc, NTP TR 421

TABLE B2
Individual Animal Tumor Pathology of Female Rats in the Lifetime Inhalation Study of Talc: 18 mg/m³

| Number of Days on Study | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| | 3 | 5 | 8 | 9 | 1 | 3 | 4 | 6 | 6 | 7 | 7 | 7 | 8 | 9 | 9 | 0 | 1 | 1 | 1 | 2 | 3 | 4 | 4 | 4 | 7 | |
| | 6 | 8 | 6 | 4 | 5 | 3 | 6 | 0 | 1 | 5 | 6 | 8 | 4 | 3 | 7 | 6 | 0 | 6 | 7 | 4 | 9 | 0 | 6 | 7 | 3 | |
| Carcass ID Number | 1 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 1 | 2 | 2 | 2 | 1 | 2 | 1 | 2 | 2 | |
| | 6 | 8 | 1 | 1 | 8 | 8 | 3 | 8 | 8 | 8 | 0 | 5 | 0 | 4 | 8 | 0 | 6 | 8 | 3 | 5 | 8 | 6 | 9 | 3 | 0 | |
| | 7 | 0 | 6 | 2 | 3 | 5 | 0 | 1 | 6 | 8 | 7 | 5 | 8 | 0 | 9 | 6 | 0 | 2 | 6 | 6 | 1 | 3 | 2 | 9 | 9 | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| Alimentary System | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Intestine large | + | + | A | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Intestine large, cecum | + | + | A | + | + | A | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | A | + | + | | |
| Intestine large, colon | + | + | A | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | | |
| Intestine large, rectum | + | M | A | M | + | A | + | + | + | + | + | M | + | + | + | + | + | + | + | M | + | + | + | + | | |
| Intestine small | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Intestine small, duodenum | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | | |
| Intestine small, ileum | + | + | A | + | + | A | + | + | + | + | + | A | + | A | + | + | + | + | A | + | A | + | A | + | + | |
| Intestine small, jejunum | + | + | A | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Granulosa-theca tumor malignant, metastatic, ovary | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Neoplastic nodule | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Pharynx | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Squamous cell carcinoma | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Fibrosarcoma | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Stomach, forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Stomach, glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Cardiovascular System | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Blood vessel | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Granulosa-theca tumor malignant, metastatic, ovary | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Endocrine System | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Adrenal gland | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Adrenal gland, cortex | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Granulosa-theca tumor malignant, metastatic, ovary | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Adrenal gland, medulla | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Granulosa-theca tumor malignant, metastatic, ovary | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pheochromocytoma malignant | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pheochromocytoma benign | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bilateral, pheochromocytoma malignant | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bilateral, pheochromocytoma benign | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, pancreatic | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Adenoma | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Parathyroid gland | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |

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Lesions in Female Rats

B-19

TABLE B2
Individual Animal Tumor Pathology of Female Rats in the Lifetime Inhalation Study of Talc: 18 mg/m³ (continued)

| Number of Days on Study | 7 7 7 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 | | | | | | | | | | | | | | | | | | | | Total Tissues/ Tumors | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-----------------------------|---|---|---|---|----|
| | 8 8 9 0 2 2 2 2 3 4 4 4 5 5 5 6 6 6 6 6 6 6 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4 6 6 3 2 3 8 9 5 1 1 2 8 0 4 7 2 2 2 2 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Carcass ID Number | 2 2 2 2 1 1 1 2 2 1 1 2 2 2 2 1 1 1 1 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 8 3 5 6 6 5 7 1 9 9 0 5 6 3 6 5 6 6 8 3 3 5 5 8 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 3 3 2 4 7 7 5 0 1 5 8 4 1 5 8 3 6 2 2 8 4 9 6 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alimentary System | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Esophagus | + | | | | | | | | | | | | | | | | | | | | 50 | | | | | |
| Intestine large | + + + + + A + + + + + + + + + + A + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | 46 | | | | | |
| Intestine large, cecum | A + + + + + A + + + + + + + + + + A + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | 43 | | | | | |
| Intestine large, colon | + + + + + A + + + + + + + + + + A + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | 45 | | | | | |
| Intestine large, rectum | + + + + + A + + M + + + + + A + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | 41 | | | | | |
| Intestine small | + + + + + A + | | | | | | | | | | | | | | | | | | | | 48 | | | | | |
| Intestine small, duodenum | + + + + + A + | | | | | | | | | | | | | | | | | | | | 47 | | | | | |
| Intestine small, ileum | A + + + + + A + + + + + A + + + + + A + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | 38 | | | | | |
| Intestine small, jejunum | + + + + + A + | | | | | | | | | | | | | | | | | | | | 46 | | | | | |
| Liver | + | | | | | | | | | | | | | | | | | | | | 50 | | | | | |
| Granulosa-theca tumor malignant, metastatic, ovary | | | | | | | | | | | | | | | | | | | | | 1 | | | | | |
| Neoplastic nodule | | | | | | | | | | | | | | | | | | | | | X | 1 | | | | |
| Pancreas | + | | | | | | | | | | | | | | | | | | | | 49 | | | | | |
| Pharynx | | | | | | | | | | | | | | | | | | | | | 1 | | | | | |
| Squamous cell carcinoma | | | | | | | | | | | | | | | | | | | | | 1 | | | | | |
| Salivary glands | + | | | | | | | | | | | | | | | | | | | | 50 | | | | | |
| Fibrosarcoma | | | | | | | | | | | | | | | | | | | | | X | 1 | | | | |
| Stomach | + | | | | | | | | | | | | | | | | | | | | 50 | | | | | |
| Stomach, forestomach | + + + + + + + + + + M + + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | 49 | | | | | |
| Stomach, glandular | + | | | | | | | | | | | | | | | | | | | | 50 | | | | | |
| Cardiovascular System | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Blood vessel | | | | | | | | | | | | | | | | | | | | | + | 1 | | | | |
| Heart | + | | | | | | | | | | | | | | | | | | | | 50 | | | | | |
| Granulosa-theca tumor malignant, metastatic, ovary | | | | | | | | | | | | | | | | | | | | | 1 | | | | | |
| Endocrine System | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Adrenal gland | + | | | | | | | | | | | | | | | | | | | | 49 | | | | | |
| Adrenal gland, cortex | + | | | | | | | | | | | | | | | | | | | | 49 | | | | | |
| Granulosa-theca tumor malignant, metastatic, ovary | | | | | | | | | | | | | | | | | | | | | 1 | | | | | |
| Adrenal gland, medulla | + | | | | | | | | | | | | | | | | | | | | 49 | | | | | |
| Granulosa-theca tumor malignant, metastatic, ovary | | | | | | | | | | | | | | | | | | | | | 1 | | | | | |
| Pheochromocytoma malignant | X | | | | | | | | | | | | | | | | | | | | X | X | X | X | X | 7 |
| Pheochromocytoma benign | | | | | | | | | | | | | | | | | | | | | X | X | X | X | X | 11 |
| Bilateral, pheochromocytoma malignant | | | | | | | | | | | | | | | | | | | | | X | X | X | X | X | 3 |
| Bilateral, pheochromocytoma benign | | | | | | | | | | | | | | | | | | | | | X | X | X | X | X | 7 |
| Islets, pancreatic | + | | | | | | | | | | | | | | | | | | | | 49 | | | | | |
| Adenoma | | | | | | | | | | | | | | | | | | | | | 1 | | | | | |
| Parathyroid gland | + + + + + M + + + + + + + + + + M + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | 47 | | | | | |

B-20

Talc, NTP TR 421

TABLE B2
Individual Animal Tumor Pathology of Female Rats in the Lifetime Inhalation Study of Talc: 18 mg/m³ (continued)

| | |
|--|---|
| Number of Days on Study | 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 7 7 7 7 |
| | 3 5 8 9 1 3 4 6 6 7 7 7 8 9 9 0 1 1 1 2 3 4 4 4 7 |
| | 6 8 6 4 5 3 6 0 1 5 6 8 4 3 7 6 0 6 7 4 9 0 6 7 3 |
| Carcass ID Number | 1 2 2 2 1 2 2 2 1 2 2 2 2 2 1 2 1 2 2 2 1 2 1 2 2 |
| | 6 8 1 1 8 8 3 8 8 8 0 5 0 4 8 0 6 8 3 5 8 6 9 3 0 |
| | 7 0 6 2 3 5 0 1 6 8 7 5 8 0 9 6 0 2 6 6 1 3 2 9 9 |
| | 1 |
| Endocrine System (continued) | |
| Pituitary gland | + |
| Pars distalis, adenoma | X X X X X |
| Pars distalis, carcinoma | X |
| Thyroid gland | + + A + |
| C-cell, adenoma | X X |
| C-cell, carcinoma | X X |
| General Body System | |
| None | |
| Genital System | |
| Clitoral gland | + M + M + |
| Adenoma | |
| Carcinoma | |
| Ovary | + |
| Bilateral, granulosa-theca tumor | |
| malignant | X |
| Uterus | + |
| Polyp stromal | X |
| Hematopoietic System | |
| Bone marrow | + + A + |
| Lymph node | + |
| Lymph node, bronchial | + + + + + + + + + + + M + + M + + + + M + + + + + |
| Squamous cell carcinoma, metastatic, lung | X |
| Lymph node, mandibular | + + + + + + + M + + + + + + + + + + + + + + + M + + |
| Lymph node, mediastinal | + |
| Carcinoma, metastatic, uncertain primary site | |
| Fibrosarcoma, metastatic, skin | X |
| Granulosa-theca tumor malignant, metastatic, ovary | X |
| Lymph node, mesenteric | + + A + |
| Spleen | + |
| Thymus | + + + M M + + + + + + + + + + + + + + + + + + |
| Schwannoma benign | |

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B-22

Talc, NTP TR 421

TABLE B2
Individual Animal Tumor Pathology of Female Rats in the Lifetime Inhalation Study of Talc: 18 mg/m³ (continued)

| | |
|--|---|
| Number of Days on Study | 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 7 7 7 7 |
| | 3 5 8 9 1 3 4 6 6 7 7 7 8 9 9 0 1 1 1 2 3 4 4 4 7 |
| | 6 8 6 4 5 3 6 0 1 5 6 8 4 3 7 6 0 6 7 4 9 0 6 7 3 |
| Carcass ID Number | 1 2 2 2 1 2 2 2 1 2 2 2 2 2 1 2 1 2 2 2 1 2 1 2 2 |
| | 6 8 1 1 8 8 3 8 8 8 0 5 0 4 8 0 6 8 3 5 8 6 9 3 0 |
| | 7 0 6 2 3 5 0 1 6 8 7 5 8 0 9 6 0 2 6 6 1 3 2 9 9 |
| | 1 |
| Integumentary System | |
| Mammary gland | + |
| Adenocarcinoma | |
| Adenoma | |
| Fibroadenoma | |
| Fibrosarcoma | |
| Skin | + |
| Keratoacanthoma | X |
| Subcutaneous tissue, fibrosarcoma | X |
| Musculoskeletal System | |
| Bone | + |
| Nervous System | |
| Brain | + |
| Carcinoma, metastatic, pituitary gland | X |
| Respiratory System | |
| Larynx | + + + + + I + I + + + + + + + + + + + + + + + + |
| Lung | + |
| Alveolar/bronchiolar adenoma | |
| Alveolar/bronchiolar adenoma, multiple | |
| Alveolar/bronchiolar carcinoma | |
| Alveolar/bronchiolar carcinoma, multiple | |
| Granulosa-theca tumor malignant, metastatic, ovary | |
| Squamous cell carcinoma | |
| Nose | + + + + + + + + + + + + + + + + + A + + + + + + + + |
| Trachea | + |
| Special Senses System | |
| Eye | |
| Harderian gland | |
| Lacrimal gland | + |
| Urinary System | |
| Kidney | + + A + |
| Urinary bladder | + |
| Systemic Lesions | |
| Multiple organs | + |
| Leukemia mononuclear | X X X X X X X X X X X X X X X X X X |

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Lesions in Female Rats

B-23

TABLE B2
 Individual Animal Tumor Pathology of Female Rats in the Lifetime Inhalation Study of Talc: 18 mg/m³ (continued)

| Number of Days on Study | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----------------------------|
| | 8 | 8 | 9 | 0 | 2 | 2 | 2 | 2 | 3 | 4 | 4 | 4 | 4 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | |
| | 4 | 6 | 6 | 3 | 2 | 3 | 8 | 9 | 5 | 1 | 1 | 2 | 8 | 0 | 4 | 7 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| Carcass ID Number | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | Total Tissues/ Tumors |
| 5 | 8 | 3 | 5 | 6 | 6 | 5 | 7 | 1 | 9 | 9 | 0 | 5 | 6 | 3 | 6 | 5 | 6 | 6 | 8 | 3 | 3 | 5 | 5 | 8 | | | | | | | | | | | | | | | |
| 7 | 7 | 3 | 3 | 2 | 4 | 7 | 7 | 5 | 0 | 1 | 5 | 8 | 4 | 1 | 5 | 8 | 3 | 6 | 2 | 2 | 8 | 4 | 9 | 6 | | | | | | | | | | | | | | | |
| 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | |
| Integumentary System | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Adenocarcinoma | | | | X | | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Adenoma | | | | | | | X | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Fibroadenoma | | | | | | | X | X | X | | | | X | | | | | | X | X | X | | X | | | | | | | | | | | | | | | 13 | |
| Fibrosarcoma | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Keratoacanthoma | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Subcutaneous tissue, fibrosarcoma | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Musculoskeletal System | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Nervous System | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Carcinoma, metastatic, pituitary gland | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Respiratory System | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Larynx | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Alveolar/bronchiolar adenoma | | X | | | | | X | X | | X | | | | X | | | | | | | | X | | | | | | | | | | | | | | | | 8 | |
| Alveolar/bronchiolar adenoma, multiple | | | | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Alveolar/bronchiolar carcinoma | | | | | | | X | | | | | | | X | | | | | | | | X | X | | | | | | | | | | | | | | | 4 | |
| Alveolar/bronchiolar carcinoma, multiple | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Granulosa-theca tumor malignant, metastatic, ovary | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Squamous cell carcinoma | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Nose | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Special Senses System | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eye | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Harderian gland | + | | | | | | | | | | | | | | | + | + | + | | + | | | | | | | | | | | | | | | | | | 15 | |
| Lacrimal gland | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Urinary System | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Urinary bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Systemic Lesions | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Multiple organs | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Leukemia mononuclear | | X | X | | | | X | | X | | | | | | | | | | X | | | | | | | | | | X | X | | | | | | | | 18 | |

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B-24

Talc, NTP TR 421

TABLE B3
Statistical Analysis of Primary Neoplasms in Female Rats in the Lifetime Inhalation Study of Talc

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|--|---------------------|---------------------|----------------------|
| Adrenal Medulla: Benign Pheochromocytoma | | | |
| Overall rates ^a | 13/48 (27%) | 14/47 (30%) | 18/49 (37%) |
| Adjusted rates ^b | 61.3% | 59.7% | 82.5% |
| Terminal rates ^c | 5/11 (45%) | 5/13 (38%) | 6/9 (67%) |
| First incidence (days) | 678 | 705 | 697 |
| Life table tests ^d | P=0.135 | P=0.529 | P=0.183 |
| Logistic regression tests ^d | P=0.185 | P=0.541 | P=0.225 |
| Cochran-Armitage test ^d | P=0.180 | | |
| Fisher exact test ^e | | P=0.474 | P=0.212 |
| Adrenal Medulla: Malignant Pheochromocytoma | | | |
| Overall rates | 0/48 (0%) | 1/47 (2%) | 10/49 (20%) |
| Adjusted rates | 0.0% | 7.1% | 56.9% |
| Terminal rates | 0/11 (0%) | 0/13 (0%) | 3/9 (33%) |
| First incidence (days) | - ^e | 849 | 784 |
| Life table tests | P<0.001 | P=0.531 | P=0.002 |
| Logistic regression tests | P<0.001 | P=0.509 | P=0.001 |
| Cochran-Armitage test | P<0.001 | | |
| Fisher exact test | | P=0.495 | P<0.001 |
| Adrenal Medulla: Benign or Malignant Pheochromocytoma | | | |
| Overall rates | 13/48 (27%) | 14/47 (30%) | 23/49 (47%) |
| Adjusted rates | 61.3% | 59.7% | 95.2% |
| Terminal rates | 5/11 (45%) | 5/13 (38%) | 8/9 (89%) |
| First incidence (days) | 678 | 705 | 697 |
| Life table tests | P=0.016 | P=0.529 | P=0.033 |
| Logistic regression tests | P=0.014 | P=0.541 | P=0.024 |
| Cochran-Armitage test | P=0.021 | | |
| Fisher exact test | | P=0.474 | P=0.034 |
| Liver: Neoplastic Nodule | | | |
| Overall rates | 0/50 (0%) | 3/48 (6%) | 1/50 (2%) |
| Adjusted rates | 0.0% | 13.6% | 10.0% |
| Terminal rates | 0/11 (0%) | 0/13 (0%) | 0/9 (0%) |
| First incidence (days) | - | 724 | 857 |
| Life table tests | P=0.550 | P=0.114 | P=0.464 |
| Logistic regression tests | P=0.561 | P=0.117 | P=0.496 |
| Cochran-Armitage test | P=0.556 | | |
| Fisher exact test | | P=0.114 | P=0.500 |
| Liver: Neoplastic Nodule or Hepatocellular Carcinoma | | | |
| Overall rates | 0/50 (0%) | 4/48 (8%) | 1/50 (2%) |
| Adjusted rates | 0.0% | 20.2% | 10.0% |
| Terminal rates | 0/11 (0%) | 1/13 (8%) | 0/9 (0%) |
| First incidence (days) | - | 724 | 857 |
| Life table tests | P=0.575 | P=0.066 | P=0.464 |
| Logistic regression tests | P=0.602 | P=0.060 | P=0.496 |
| Cochran-Armitage test | P=0.599 | | |
| Fisher exact test | | P=0.054 | P=0.500 |

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Lesions in Female Rats

B-25

TABLE B3
Statistical Analysis of Primary Neoplasms in Female Rats in the Lifetime Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|---|---------------------|---------------------|----------------------|
| Lung: Alveolar/bronchiolar Adenoma | | | |
| Overall rates | 1/50 (2%) | 0/48 (0%) | 9/50 (18%) |
| Adjusted rates | 4.5% | 0.0% | 40.8% |
| Terminal rates | 0/11 (0%) | 0/13 (0%) | 1/9 (11%) |
| First incidence (days) | 805 | - | 716 |
| Life table tests | P<0.001 | P=0.529N | P=0.015 |
| Logistic regression tests | P<0.001 | P=0.503N | P=0.010 |
| Cochran-Armitage test | P<0.001 | | |
| Fisher exact test | | P=0.510N | P=0.008 |
| Lung: Alveolar/bronchiolar Carcinoma | | | |
| Overall rates | 0/50 (0%) | 0/48 (0%) | 5/50 (10%) |
| Adjusted rates | 0.0% | 0.0% | 41.7% |
| Terminal rates | 0/11 (0%) | 0/13 (0%) | 3/9 (33%) |
| First incidence (days) | - | - | 828 |
| Life table tests | P=0.002 | - ^f | P=0.027 |
| Logistic regression tests | P=0.003 | - | P=0.028 |
| Cochran-Armitage test | P=0.004 | | |
| Fisher exact test | | - | P=0.028 |
| Lung: Alveolar/bronchiolar Adenoma or Carcinoma | | | |
| Overall rates | 1/50 (2%) | 0/48 (0%) | 13/50 (26%) |
| Adjusted rates | 4.5% | 0.0% | 65.8% |
| Terminal rates | 0/11 (0%) | 0/13 (0%) | 4/9 (44%) |
| First incidence (days) | 805 | - | 716 |
| Life table tests | P<0.001 | P=0.529N | P=0.001 |
| Logistic regression tests | P<0.001 | P=0.503N | P<0.001 |
| Cochran-Armitage test | P<0.001 | | |
| Fisher exact test | | P=0.510N | P<0.001 |
| Mammary Gland: Fibroadenoma | | | |
| Overall rates | 11/50 (22%) | 10/49 (20%) | 13/50 (26%) |
| Adjusted rates | 47.6% | 41.4% | 64.0% |
| Terminal rates | 2/11 (18%) | 3/13 (23%) | 4/9 (44%) |
| First incidence (days) | 634 | 482 | 678 |
| Life table tests | P=0.304 | P=0.489N | P=0.394 |
| Logistic regression tests | P=0.363 | P=0.508N | P=0.428 |
| Cochran-Armitage test | P=0.343 | | |
| Fisher exact test | | P=0.521N | P=0.408 |
| Mammary Gland: Fibroma, Fibroadenoma, or Adenoma | | | |
| Overall rates | 13/50 (26%) | 13/49 (27%) | 15/50 (30%) |
| Adjusted rates | 54.7% | 59.0% | 68.6% |
| Terminal rates | 3/11 (27%) | 6/13 (46%) | 4/9 (44%) |
| First incidence (days) | 634 | 482 | 678 |
| Life table tests | P=0.314 | P=0.544N | P=0.404 |
| Logistic regression tests | P=0.394 | P=0.585 | P=0.434 |
| Cochran-Armitage test | P=0.371 | | |
| Fisher exact test | | P=0.567 | P=0.412 |

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B-26

Talc, NTP TR 421

TABLE B3
Statistical Analysis of Primary Neoplasms in Female Rats in the Lifetime Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|---|---------------------|---------------------|----------------------|
| Mammary Gland: Fibroma, Fibroadenoma, Adenoma, or Adenocarcinoma | | | |
| Overall rates | 15/50 (30%) | 13/49 (27%) | 16/50 (32%) |
| Adjusted rates | 56.6% | 59.0% | 70.1% |
| Terminal rates | 3/11 (27%) | 6/13 (46%) | 4/9 (44%) |
| First incidence (days) | 370 | 482 | 678 |
| Life table tests | P=0.378 | P=0.386N | P=0.494 |
| Logistic regression tests | P=0.457 | P=0.425N | P=0.531 |
| Cochran-Armitage test | P=0.430 | | |
| Fisher exact test | | P=0.437N | P=0.500 |
| Pituitary Gland (Pars Distalis): Adenoma | | | |
| Overall rates | 19/50 (38%) | 18/47 (38%) | 21/50 (42%) |
| Adjusted rates | 62.1% | 60.5% | 78.3% |
| Terminal rates | 3/11 (27%) | 3/13 (23%) | 4/9 (44%) |
| First incidence (days) | 568 | 697 | 633 |
| Life table tests | P=0.360 | P=0.512N | P=0.425 |
| Logistic regression tests | P=0.409 | P=0.557N | P=0.457 |
| Cochran-Armitage test | P=0.380 | | |
| Fisher exact test | | P=0.571 | P=0.419 |
| Pituitary Gland (Pars Distalis): Carcinoma | | | |
| Overall rates | 3/50 (6%) | 3/47 (6%) | 2/50 (4%) |
| Adjusted rates | 17.1% | 12.2% | 5.6% |
| Terminal rates | 1/11 (9%) | 1/13 (8%) | 0/9 (0%) |
| First incidence (days) | 696 | 566 | 676 |
| Life table tests | P=0.438N | P=0.636N | P=0.506N |
| Logistic regression tests | P=0.427N | P=0.634 | P=0.497N |
| Cochran-Armitage test | P=0.418N | | |
| Fisher exact test | | P=0.631 | P=0.500N |
| Pituitary Gland (Pars Distalis): Adenoma or Carcinoma | | | |
| Overall rates | 22/50 (44%) | 21/47 (45%) | 23/50 (46%) |
| Adjusted rates | 69.8% | 66.2% | 79.5% |
| Terminal rates | 4/11 (36%) | 4/13 (31%) | 4/9 (44%) |
| First incidence (days) | 568 | 566 | 633 |
| Life table tests | P=0.429 | P=0.502N | P=0.488 |
| Logistic regression tests | P=0.506 | P=0.570N | P=0.545 |
| Cochran-Armitage test | P=0.471 | | |
| Fisher exact test | | P=0.554 | P=0.500 |
| Thyroid Gland (C-cell): Adenoma | | | |
| Overall rates | 5/50 (10%) | 0/47 (0%) | 6/49 (12%) |
| Adjusted rates | 33.5% | 0.0% | 34.0% |
| Terminal rates | 2/11 (18%) | 0/13 (0%) | 2/9 (22%) |
| First incidence (days) | 805 | - | 678 |
| Life table tests | P=0.253 | P=0.030N | P=0.467 |
| Logistic regression tests | P=0.283 | P=0.029N | P=0.505 |
| Cochran-Armitage test | P=0.276 | | |
| Fisher exact test | | P=0.033N | P=0.486 |

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Lesions in Female Rats

B-27

TABLE B3
Statistical Analysis of Primary Neoplasms in Female Rats in the Lifetime Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|---|---------------------|---------------------|----------------------|
| Thyroid Gland (C-cell): Carcinoma | | | |
| Overall rates | 3/50 (6%) | 2/47 (4%) | 2/49 (4%) |
| Adjusted rates | 11.1% | 12.2% | 4.9% |
| Terminal rates | 0/11 (0%) | 0/13 (0%) | 0/9 (0%) |
| First incidence (days) | 677 | 818 | 675 |
| Life table tests | P=0.430N | P=0.507N | P=0.493N |
| Logistic regression tests | P=0.462N | P=0.516N | P=0.533N |
| Cochran-Armitage test | P=0.463N | | |
| Fisher exact test | | P=0.530N | P=0.510N |
| Thyroid Gland (C-cell): Adenoma or Carcinoma | | | |
| Overall rates | 8/50 (16%) | 2/47 (4%) | 8/49 (16%) |
| Adjusted rates | 40.9% | 12.2% | 37.2% |
| Terminal rates | 2/11 (18%) | 0/13 (0%) | 2/9 (22%) |
| First incidence (days) | 677 | 818 | 675 |
| Life table tests | P=0.418 | P=0.051N | P=0.579 |
| Logistic regression tests | P=0.435 | P=0.048N | P=0.599N |
| Cochran-Armitage test | P=0.414 | | |
| Fisher exact test | | P=0.056N | P=0.590 |
| Uterus: Stromal Polyp | | | |
| Overall rates | 5/50 (10%) | 7/49 (14%) | 4/50 (8%) |
| Adjusted rates | 22.3% | 34.4% | 19.5% |
| Terminal rates | 1/11 (9%) | 3/13 (23%) | 1/9 (11%) |
| First incidence (days) | 398 | 678 | 678 |
| Life table tests | P=0.439N | P=0.400 | P=0.532N |
| Logistic regression tests | P=0.376N | P=0.372 | P=0.505N |
| Cochran-Armitage test | P=0.386N | | |
| Fisher exact test | | P=0.365 | P=0.500N |
| Uterus: Stromal Polyp or Stromal Sarcoma | | | |
| Overall rates | 5/50 (10%) | 8/49 (16%) | 4/50 (8%) |
| Adjusted rates | 22.3% | 35.8% | 19.5% |
| Terminal rates | 1/11 (9%) | 3/13 (23%) | 1/9 (11%) |
| First incidence (days) | 398 | 557 | 678 |
| Life table tests | P=0.412N | P=0.298 | P=0.532N |
| Logistic regression tests | P=0.360N | P=0.265 | P=0.505N |
| Cochran-Armitage test | P=0.363N | | |
| Fisher exact test | | P=0.264 | P=0.500N |
| All Organs: Mononuclear Cell Leukemia | | | |
| Overall rates | 13/50 (26%) | 20/49 (41%) | 18/50 (36%) |
| Adjusted rates | 45.7% | 73.3% | 60.1% |
| Terminal rates | 1/11 (9%) | 8/13 (62%) | 3/9 (33%) |
| First incidence (days) | 390 | 526 | 536 |
| Life table tests | P=0.234 | P=0.164 | P=0.232 |
| Logistic regression tests | P=0.226 | P=0.084 | P=0.152 |
| Cochran-Armitage test | P=0.250 | | |
| Fisher exact test | | P=0.088 | P=0.194 |

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B-28

Talc, NTP TR 421

TABLE B3
Statistical Analysis of Primary Neoplasms in Female Rats in the Lifetime Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|---|---------------------|---------------------|----------------------|
| All Organs: Malignant Lymphoma | | | |
| Overall rates | 0/50 (0%) | 3/49 (6%) | 0/50 (0%) |
| Adjusted rates | 0.0% | 10.3% | 0.0% |
| Terminal rates | 0/11 (0%) | 0/13 (0%) | 0/9 (0%) |
| First incidence (days) | - | 724 | - |
| Life table tests | P=0.525N | P=0.124 | - |
| Logistic regression tests | P=0.497N | P=0.118 | - |
| Cochran-Armitage test | P=0.499N | | |
| Fisher exact test | | P=0.117 | - |
| All Organs: Benign Tumors | | | |
| Overall rates | 38/50 (76%) | 35/49 (71%) | 39/50 (78%) |
| Adjusted rates | 97.2% | 96.9% | 97.4% |
| Terminal rates | 10/11 (91%) | 12/13 (92%) | 8/9 (89%) |
| First incidence (days) | 398 | 482 | 558 |
| Life table tests | P=0.338 | P=0.350N | P=0.440 |
| Logistic regression tests | P=0.544 | P=0.312N | P=0.562N |
| Cochran-Armitage test | P=0.415 | | |
| Fisher exact test | | P=0.387N | P=0.500 |
| All Organs: Malignant Tumors | | | |
| Overall rates | 23/50 (46%) | 31/49 (63%) | 35/50 (70%) |
| Adjusted rates | 69.3% | 85.8% | 90.5% |
| Terminal rates | 4/11 (36%) | 9/13 (69%) | 6/9 (67%) |
| First incidence (days) | 370 | 526 | 536 |
| Life table tests | P=0.054 | P=0.189 | P=0.061 |
| Logistic regression tests | P=0.013 | P=0.056 | P=0.010 |
| Cochran-Armitage test | P=0.016 | | |
| Fisher exact test | | P=0.064 | P=0.013 |
| All Organs: Benign or Malignant Tumors | | | |
| Overall rates | 44/50 (88%) | 47/49 (96%) | 49/50 (98%) |
| Adjusted rates | 97.6% | 97.9% | 100.0% |
| Terminal rates | 10/11 (91%) | 12/13 (92%) | 9/9 (100%) |
| First incidence (days) | 370 | 482 | 536 |
| Life table tests | P=0.248 | P=0.447 | P=0.279 |
| Logistic regression tests | P=0.053 | P=0.145 | P=0.060 |
| Cochran-Armitage test | P=0.049 | | |
| Fisher exact test | | P=0.141 | P=0.056 |

^a Number of tumor-bearing animals/number of animals examined. Denominator is number of animals examined microscopically for adrenal gland, bone marrow, brain, clitoral gland, epididymis, gallbladder (mouse), heart, kidney, larynx, liver, lung, nose, ovary, pancreas, parathyroid gland, pituitary gland, preputial gland, prostate gland, salivary gland, spleen, testes, thyroid gland, and urinary bladder; for other tissues, denominator is number of animals necropsied.

^b Kaplan-Meier estimated tumor incidence at the end of the study after adjustment for intercurrent mortality

^c Observed incidence at terminal kill

^d Beneath the control incidence are the P values associated with the trend test. Beneath the dosed group incidence are the P values corresponding to pairwise comparisons between the controls and that dosed group. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death. The logistic regression tests regard these lesions as nonfatal. The Cochran-Armitage and Fisher exact tests compare directly the overall incidence rates. For all tests, a negative trend or a lower incidence in a dose group is indicated by N.

^e Not applicable; no tumors in animal group

^f Value of statistic cannot be computed.

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