

Lesions in Female Mice

D-17

TABLE D2 Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 6 mg/m³ (continued)

| Number of Days on Study | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|----|---|
| Number of Days on Study | 1 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | | | |
| Number of Days on Study | 4 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | | | |
| Carcass ID Number | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | | | | |
| Carcass ID Number | 8 | 2 | 2 | 3 | 0 | 5 | 5 | 7 | 7 | 0 | 8 | 8 | 0 | 1 | 3 | 4 | 4 | 6 | 6 | 6 | 7 | 4 | 7 | 8 | | | | | | | | | | | | |
| Carcass ID Number | 5 | 4 | 9 | 0 | 6 | 2 | 4 | 6 | 8 | 7 | 7 | 9 | 9 | 1 | 8 | 4 | 5 | 6 | 8 | 9 | 2 | 7 | 8 | 0 | | | | | | | | | | | | |
| Carcass ID Number | 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 | | | | |
| Total Tissues/Tumors | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Respiratory System | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Larynx | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 43 | | |
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Adenocarcinoma, metastatic, kidney | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Alveolar/bronchiolar adenoma | | | | | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Alveolar/bronchiolar carcinoma | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 4 | |
| Hepatocellular carcinoma, metastatic, liver | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Nose | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 46 | | |
| Trachea | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M M | 36 | |
| Special Senses System | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eye | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Harderian gland | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Adenoma | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Urinary System | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 46 | |
| Adenocarcinoma | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Urinary bladder | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 40 | |
| Systemic Lesions | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Multiple organs | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Lymphoma malignant lymphocytic | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Lymphoma malignant mixed | | | | X | | | | | X | X | X | | | | | | | | | | | | | | | | | | | | | | | | | 4 |

D-18

Talc, NTP TR 421

TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 18 mg/m³

| | |
|------------------------------|---|
| Number of Days on Study | 0 0 0 0 0 0 0 4 5 5 5 5 5 5 6 6 6 6 6 6 6 7 7 7 |
| | 2 2 2 2 2 2 2 7 0 1 4 5 5 6 8 4 4 5 6 6 8 9 0 1 1 |
| | 0 8 8 8 8 8 8 3 8 6 8 4 8 9 1 2 6 5 1 5 6 2 6 6 8 |
| Carcass ID Number | 2 1 2 2 2 2 2 3 3 2 2 3 3 3 2 3 2 3 2 2 2 2 2 2 2 |
| | 9 9 0 0 0 0 0 4 4 0 3 1 5 6 7 2 3 5 2 2 3 6 9 6 5 |
| | 2 6 1 3 4 6 7 9 6 2 9 6 3 0 0 8 2 2 7 8 6 6 6 7 9 |
| | 1 |
| Alimentary System | |
| Esophagus | + + + + + M + + M + + + + + + + + + + + + + + + + |
| Gallbladder | A M M A A A M M + M A A A A + A A + A A A + + A + |
| Intestine large | A A A + + A A + + A + A + A + A + A A A + + A A + |
| Intestine large, cecum | A A A + A A A + + A + A A A + A + A A A + + A A + |
| Leiomyoma | |
| Intestine large, colon | A A A + A A A I + A + A A A + A A A A + + A A + |
| Intestine large, rectum | A A A + + A A M I M M A + A + A + M A M + + M A + |
| Intestine small | A A A + A A A + + A + A + A + A + A A A A + A A + |
| Intestine small, duodenum | A A A + A A A + + A M A A A + A A A A A + A A + |
| Intestine small, ileum | A A A A A A A + A A + A A A + A + A A A A + A A + |
| Intestine small, jejunum | A A A + A A A + A A A A + A + A A A A A + A A + |
| Liver | + |
| Hepatocellular carcinoma | |
| Hepatocellular adenoma | |
| Pancreas | A + + + M A + + + A + + + A + + + + + + + + + + A + |
| Salivary glands | + |
| Stomach | + |
| Stomach, forestomach | + |
| Stomach, glandular | + + + + + + + + A + + A I + + + + A + + + + + + + |
| Cardiovascular System | |
| Heart | + |
| Endocrine System | |
| Adrenal gland | + |
| Adrenal gland, cortex | + |
| Adrenal gland, medulla | + I I M + + I + + + + + + + + + + + + + + + + + + |
| Islets, pancreatic | A + + I M A M + + M M + + I I M + + + M I I + A + |
| Parathyroid gland | + M M + + M M M M M + + + M M + + I + M M + + + |
| Pituitary gland | + + + + M I + + + + + + + + + + + + + + + + + + + |
| Adenoma | |
| Thyroid gland | + + M + |
| Follicular cell, adenoma | |
| General Body System | |
| Tissue NOS | |
| Hemangioma | + |
| Hemangiosarcoma | X |

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Lesions in Female Mice

D-19

TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 18 mg/m³ (continued)

| Number of Days on Study | 7 | | | | | | | | | | | | | | | | | | | | Total Tissues/ Tumors |
|------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-----------------------------|
| | 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 9 9 9 9 9 0 0 0 0 1 1 1 1 1 2 2 2 2 2 3 3 3 3 | | | | | | | | | | | | | | | | | | | | |
| Carcass ID Number | 2 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 2 2 2 3 3 1 2 3 3 4 6 6 8 8 9 9 9 1 1 2 2 2 5 5 5 8 9 2 5 0 9 4 8 0 0 1 6 8 4 8 9 7 9 4 6 9 4 5 8 6 9 0 2 9 1 | | | | | | | | | | | | | | | | | | | | Total Tissues/ Tumors |
| | Alimentary System | | | | | | | | | | | | | | | | | | | | |
| Esophagus | + | | | | | | | | | | | | | | | | | | | | 48 |
| Gallbladder | + + + + + M + + + + + + + + + + + + + + + M + + + + | | | | | | | | | | | | | | | | | | | | 29 |
| Intestine large | + | | | | | | | | | | | | | | | | | | | | 36 |
| Intestine large, cecum | + | | | | | | | | | | | | | | | | | | | | 34 |
| Leiomyoma | | | | | | | | | | | | | | | | | | | | | 1 |
| Intestine large, colon | + | | | | | | | | | | | | | | | | | | | | 32 |
| Intestine large, rectum | + + + + + M + M + + + M + + M M + + I + + + + + + + + | | | | | | | | | | | | | | | | | | | | 27 |
| Intestine small | + | | | | | | | | | | | | | | | | | | | | 34 |
| Intestine small, duodenum | M + M + + + M + + + + + + + + + + + + + + + M + + | | | | | | | | | | | | | | | | | | | | 27 |
| Intestine small, ileum | + | | | | | | | | | | | | | | | | | | | | 31 |
| Intestine small, jejunum | + | | | | | | | | | | | | | | | | | | | | 31 |
| Liver | + | | | | | | | | | | | | | | | | | | | | 50 |
| Hepatocellular carcinoma | X | | | | | | | | | | | | | | | | | | | | 4 |
| Hepatocellular adenoma | | | | | | | | | | | | | | | | | | | | | 4 |
| Pancreas | + | | | | | | | | | | | | | | | | | | | | 44 |
| Salivary glands | + | | | | | | | | | | | | | | | | | | | | 50 |
| Stomach | + | | | | | | | | | | | | | | | | | | | | 50 |
| Stomach, forestomach | + | | | | | | | | | | | | | | | | | | | | 50 |
| Stomach, glandular | + | | | | | | | | | | | | | | | | | | | | 46 |
| Cardiovascular System | | | | | | | | | | | | | | | | | | | | | |
| Heart | + | | | | | | | | | | | | | | | | | | | | 50 |
| Endocrine System | | | | | | | | | | | | | | | | | | | | | |
| Adrenal gland | + | | | | | | | | | | | | | | | | | | | | 50 |
| Adrenal gland, cortex | + | | | | | | | | | | | | | | | | | | | | 50 |
| Adrenal gland, medulla | + + + I + | | | | | | | | | | | | | | | | | | | | 45 |
| Islets, pancreatic | + I M I + I + I + + + M I + I + + I I + I + + M I | | | | | | | | | | | | | | | | | | | | 23 |
| Parathyroid gland | M I + + + I M M M + I + + M M + + M I M + + + M + | | | | | | | | | | | | | | | | | | | | 25 |
| Pituitary gland | + | | | | | | | | | | | | | | | | | | | | 48 |
| Adenoma | X | | | | | | | | | | | | | | | | | | | | 2 |
| Thyroid gland | + | | | | | | | | | | | | | | | | | | | | 49 |
| Follicular cell, adenoma | X X | | | | | | | | | | | | | | | | | | | | 2 |
| General Body System | | | | | | | | | | | | | | | | | | | | | |
| Tissue NOS | | | | | | | | | | | | | | | | | | | | | 2 |
| Hemangioma | + | | | | | | | | | | | | | | | | | | | | 1 |
| Hemangiosarcoma | X | | | | | | | | | | | | | | | | | | | | 1 |

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Talc, NTP TR 421

TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 18 mg/m³ (continued)

| | |
|---|---|
| Number of Days on Study | 0 0 0 0 0 0 0 4 5 5 5 5 5 5 6 6 6 6 6 6 7 7 7 |
| | 2 2 2 2 2 2 2 7 0 1 4 5 5 6 8 4 4 5 6 6 8 9 0 1 1 |
| | 0 8 8 8 8 8 8 3 8 6 8 4 8 9 1 2 6 5 1 5 6 2 6 6 8 |
| Carcass ID Number | 2 1 2 2 2 2 2 3 3 2 2 3 3 3 2 3 2 3 2 2 2 2 2 2 2 |
| | 9 9 0 0 0 0 0 4 4 0 3 1 5 6 7 2 3 5 2 2 3 6 9 6 5 |
| | 2 6 1 3 4 6 7 9 6 2 9 6 3 0 0 8 2 2 7 8 6 6 6 7 9 |
| | 1 |
| Genital System | |
| Ovary | + + + + + + + + + + + + + I + M + + M + + + + |
| Uterus | + + M + + + + + + + + + + + + + + + + + + + |
| Carcinoma adenosquamous | |
| Hematopoietic System | |
| Bone marrow | + + + + + + + A + A A + + A A + + + + + + + + + |
| Lymph node | + M + |
| Lymph node, bronchial | M M M + M M M + + I + + + + + + + + + + + + + |
| Lymph node, mandibular | + M M M + + + + + + + M M + + + + + + + + + + |
| Lymph node, mediastinal | M M M M M M M M M + M M M M M M + + + M + M + + |
| Lymph node, mesenteric | M M A + M M M + + A + A + + + M + + + + M + M + + |
| Spleen | + |
| Hemangiosarcoma | |
| Thymus | M M + M + + M M + + + + + + + + + + + + M + + M I |
| Integumentary System | |
| Mammary gland | + + M + + + + + + + + I + + + + + + + + + + + |
| Fibrosarcoma | |
| Skin | + |
| Musculoskeletal System | |
| Bone | + |
| Nervous System | |
| Brain | + |
| Spinal cord | |
| Thoracic, ganglioneuroma | |
| Respiratory System | |
| Larynx | + + M + |
| Lung | + |
| Alveolar/bronchiolar adenoma | |
| Alveolar/bronchiolar carcinoma | |
| Hemangiosarcoma, metastatic, tissue NOS | |
| Nose | + |
| Trachea | + + + + + + + + + + + + + + + + A + M + + + + + + + |

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TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 18 mg/m³ (continued)

| | | | |
|---|---|---|-----------------------------|
| Number of Days on Study | 7 | | |
| | 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 | | |
| | 9 9 9 9 9 0 0 0 1 1 1 1 1 1 2 2 2 2 2 2 3 3 3 3 | | |
| Carcass ID Number | 2 2 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 2 2 2 3 3 | | Total Tissues/Tumors |
| | 1 2 3 3 4 6 6 8 8 9 9 9 1 1 2 2 2 5 5 5 5 8 9 2 5 | | |
| | 0 9 4 8 0 0 1 6 8 4 8 9 7 9 4 6 9 4 5 8 6 9 0 2 9 | | |
| Gential System | | | |
| Ovary | + + + + + + + + + + + + + + M + + + + + + + + | | 46 |
| Uterus | + | | 49 |
| Carcinoma adenosquamous | | X | 1 |
| Hematopoietic System | | | |
| Bone marrow | + | | 45 |
| Lymph node | + | | 49 |
| Lymph node, bronchial | + | | 43 |
| Lymph node, mandibular | M + + M I M + + M + + + + + M M + + + + + M + M + | | 36 |
| Lymph node, mediastinal | M M M M M M M + M + + M + M M M M + M + + M M | | 14 |
| Lymph node, mesenteric | M + | | 37 |
| Spleen | + | | 50 |
| Hemangiosarcoma | | X | 1 |
| Thymus | + 1 | | 41 |
| Integumentary System | | | |
| Mammary gland | + | | 48 |
| Fibrosarcoma | | X | 1 |
| Skin | + | | 50 |
| Musculoskeletal System | | | |
| Bone | + | | 50 |
| Nervous System | | | |
| Brain | + | | 50 |
| Spinal cord | + | | 1 |
| Thoracic, ganglioneuroma | X | | 1 |
| Respiratory System | | | |
| Larynx | I + | | 48 |
| Lung | + | | 50 |
| Alveolar/bronchiolar adenoma | | X | 2 |
| Alveolar/bronchiolar carcinoma | | | 1 |
| Hemangiosarcoma, metastatic, tissue NOS | | | 1 |
| Nose | + | | 50 |
| Trachea | M + + + + + + + + + + + + + M I + + + + + + + + + + | | 45 |

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Talc, NTP TR 421

TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 18 mg/m³ (continued)

| | |
|---|---|
| Number of Days on Study | 0 0 0 0 0 0 0 4 5 5 5 5 5 5 6 6 6 6 6 6 6 7 7 7 |
| | 2 2 2 2 2 2 2 7 0 1 4 5 5 6 8 4 4 5 6 6 8 9 0 1 1 |
| | 0 8 8 8 8 8 8 3 8 6 8 4 8 9 1 2 6 5 1 5 6 2 6 6 8 |
| Carcass ID Number | 2 1 2 2 2 2 2 3 3 2 2 3 3 3 2 3 2 3 2 2 2 2 2 2 2 |
| | 9 9 0 0 0 0 0 4 4 0 3 1 5 6 7 2 3 5 2 2 3 6 9 6 5 |
| | 2 6 1 3 4 6 7 9 6 2 9 6 3 0 0 8 2 2 7 8 6 6 6 7 9 |
| | 1 |
| Special Senses System | |
| Harderian gland | |
| Adenocarcinoma | + |
| | X |
| Urinary System | |
| Kidney | + |
| Urinary bladder | A A + + + + A + + + + A + + + + A + A + + + A + A + + |
| Systemic Lesions | |
| Multiple organs | + |
| Lymphoma malignant histiocytic | |
| Lymphoma malignant lymphocytic | X |
| Lymphoma malignant mixed | |
| Lymphoma malignant undifferentiated cell type | X |

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Lesions in Female Mice

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TABLE D2
Individual Animal Tumor Pathology of Female Mice in the 2-Year Inhalation Study of Talc: 18 mg/m³ (continued)

| | | |
|---|--|-----------------------------|
| Number of Days on Study | 7 | |
| | 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 | |
| | 9 9 9 9 9 0 0 0 0 1 1 1 1 1 2 2 2 2 2 2 3 3 3 3 | |
| Carcass ID Number | 2 2 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 2 2 2 3 3 1 2 3 3 4 6 6 8 8 9 9 9 1 1 2 2 2 5 5 5 5 8 9 2 5 0 9 4 8 0 0 1 6 8 4 8 9 7 9 4 6 9 4 5 8 6 9 0 2 9 1 | Total Tissues/ Tumors |
| Special Senses System | | |
| Harderian gland | | 1 |
| Adenocarcinoma | | 1 |
| Urinary System | | |
| Kidney | + | 50 |
| Urinary bladder | + | 41 |
| Systemic Lesions | | |
| Multiple organs | + | 50 |
| Lymphoma malignant histiocytic | | 1 |
| Lymphoma malignant lymphocytic | | 3 |
| Lymphoma malignant mixed | | 2 |
| Lymphoma malignant undifferentiated cell type | | 2 |

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Talc, NTP TR 421

TABLE D3
Statistical Analysis of Primary Neoplasms in Female Mice in the 2-Year Inhalation Study of Talc

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|---|---------------------|---------------------|----------------------|
| Liver: Hepatocellular Adenoma | | | |
| Overall rates ^a | 5/46 (11%) | 1/47 (2%) | 4/50 (8%) |
| Adjusted rates ^b | 16.7% | 4.3% | 14.0% |
| Terminal rates ^c | 5/30 (17%) | 1/23 (4%) | 2/25 (8%) |
| First incidence (days) | 729 (T) | 729 (T) | 581 |
| Life table tests ^d | P=0.565 | P=0.169N | P=0.602N |
| Logistic regression tests ^d | P=0.603N | P=0.169N | P=0.539N |
| Cochran-Armitage test ^d | P=0.523N | | |
| Fisher exact test ^d | | P=0.097N | P=0.447N |
| Liver: Hepatocellular Carcinoma | | | |
| Overall rates | 7/46 (15%) | 5/47 (11%) | 4/50 (8%) |
| Adjusted rates | 19.1% | 18.4% | 15.4% |
| Terminal rates | 3/30 (10%) | 3/23 (13%) | 3/25 (12%) |
| First incidence (days) | 426 | 645 | 718 |
| Life table tests | P=0.308N | P=0.487N | P=0.344N |
| Logistic regression tests | P=0.243N | P=0.372N | P=0.255N |
| Cochran-Armitage test | P=0.197N | | |
| Fisher exact test | | P=0.364N | P=0.216N |
| Liver: Hepatocellular Adenoma or Carcinoma | | | |
| Overall rates | 11/46 (24%) | 6/47 (13%) | 7/50 (14%) |
| Adjusted rates | 31.1% | 22.5% | 25.2% |
| Terminal rates | 7/30 (23%) | 4/23 (17%) | 5/25 (20%) |
| First incidence (days) | 426 | 645 | 581 |
| Life table tests | P=0.329N | P=0.262N | P=0.330N |
| Logistic regression tests | P=0.253N | P=0.147N | P=0.227N |
| Cochran-Armitage test | P=0.184N | | |
| Fisher exact test | | P=0.131N | P=0.163N |
| Lung: Alveolar/bronchiolar Adenoma | | | |
| Overall rates | 3/46 (7%) | 2/49 (4%) | 2/50 (4%) |
| Adjusted rates | 10.0% | 6.7% | 6.4% |
| Terminal rates | 3/30 (10%) | 1/23 (4%) | 1/25 (4%) |
| First incidence (days) | 729 (T) | 559 | 548 |
| Life table tests | P=0.505N | P=0.589N | P=0.562N |
| Logistic regression tests | P=0.467N | P=0.499N | P=0.515N |
| Cochran-Armitage test | P=0.425N | | |
| Fisher exact test | | P=0.470N | P=0.460N |
| Lung: Alveolar/bronchiolar Carcinoma | | | |
| Overall rates | 2/46 (4%) | 4/49 (8%) | 1/50 (2%) |
| Adjusted rates | 6.7% | 11.6% | 2.6% |
| Terminal rates | 2/30 (7%) | 0/23 (0%) | 0/25 (0%) |
| First incidence (days) | 729 (T) | 491 | 558 |
| Life table tests | P=0.383N | P=0.286 | P=0.539N |
| Logistic regression tests | P=0.325N | P=0.356 | P=0.500N |
| Cochran-Armitage test | P=0.309N | | |
| Fisher exact test | | P=0.369 | P=0.468N |

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TABLE D3
Statistical Analysis of Primary Neoplasms in Female Mice in the 2-Year Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|---|---------------------|---------------------|----------------------|
| Lung: Alveolar/bronchiolar Adenoma or Carcinoma | | | |
| Overall rates | 5/46 (11%) | 6/49 (12%) | 3/50 (6%) |
| Adjusted rates | 16.7% | 17.5% | 8.9% |
| Terminal rates | 5/30 (17%) | 1/23 (4%) | 1/25 (4%) |
| First incidence (days) | 729 (T) | 491 | 548 |
| Life table tests | P=0.337N | P=0.394 | P=0.428N |
| Logistic regression tests | P=0.269N | P=0.519 | P=0.367N |
| Cochran-Armitage test | P=0.235N | | |
| Fisher exact test | | P=0.545 | P=0.311N |
| Ovary: Luteoma | | | |
| Overall rates | 2/38 (5%) | 0/43 (0%) | 0/46 (0%) |
| Adjusted rates | 8.0% | 0.0% | 0.0% |
| Terminal rates | 2/25 (8%) | 0/21 (0%) | 0/24 (0%) |
| First incidence (days) | 729 (T) | - ^e | - |
| Life table tests | P=0.177N | P=0.277N | P=0.246N |
| Logistic regression tests | P=0.177N | P=0.277N | P=0.246N |
| Cochran-Armitage test | P=0.146N | | |
| Fisher exact test | | P=0.217N | P=0.202N |
| Pituitary Gland (Unspecified Site): Adenoma | | | |
| Overall rates | 5/42 (12%) | 4/43 (9%) | 2/48 (4%) |
| Adjusted rates | 15.1% | 18.2% | 7.1% |
| Terminal rates | 2/30 (7%) | 4/22 (18%) | 1/25 (4%) |
| First incidence (days) | 683 | 729 (T) | 665 |
| Life table tests | P=0.239N | P=0.610 | P=0.290N |
| Logistic regression tests | P=0.189N | P=0.604N | P=0.220N |
| Cochran-Armitage test | P=0.133N | | |
| Fisher exact test | | P=0.485N | P=0.166N |
| Pituitary Gland (Unspecified Site): Carcinoma | | | |
| Overall rates | 0/42 (0%) | 2/43 (5%) | 0/48 (0%) |
| Adjusted rates | 0.0% | 5.5% | 0.0% |
| Terminal rates | 0/30 (0%) | 0/22 (0%) | 0/25 (0%) |
| First incidence (days) | - | 534 | - |
| Life table tests | P=0.591N | P=0.237 | - ^f |
| Logistic regression tests | P=0.515N | P=0.274 | - |
| Cochran-Armitage test | P=0.542N | | |
| Fisher exact test | | P=0.253 | - |
| Pituitary Gland (Unspecified Site): Adenoma or Carcinoma | | | |
| Overall rates | 5/42 (12%) | 6/43 (14%) | 2/48 (4%) |
| Adjusted rates | 15.1% | 22.7% | 7.1% |
| Terminal rates | 2/30 (7%) | 4/22 (18%) | 1/25 (4%) |
| First incidence (days) | 683 | 534 | 665 |
| Life table tests | P=0.216N | P=0.352 | P=0.290N |
| Logistic regression tests | P=0.150N | P=0.451 | P=0.220N |
| Cochran-Armitage test | P=0.111N | | |
| Fisher exact test | | P=0.517 | P=0.166N |

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Talc, NTP TR 421

TABLE D3
Statistical Analysis of Primary Neoplasms in Female Mice in the 2-Year Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|--|---------------------|---------------------|----------------------|
| All Organs: Hemangioma or Hemangiosarcoma | | | |
| Overall rates | 2/46 (4%) | 1/49 (2%) | 3/50 (6%) |
| Adjusted rates | 6.7% | 4.3% | 10.1% |
| Terminal rates | 2/30 (7%) | 1/23 (4%) | 2/25 (8%) |
| First incidence (days) | 729 (T) | 729 (T) | 473 |
| Life table tests | P=0.323 | P=0.593N | P=0.434 |
| Logistic regression tests | P=0.356 | P=0.593N | P=0.495 |
| Cochran-Armitage test | P=0.399 | | |
| Fisher exact test | | P=0.476N | P=0.540 |
| All Organs: Malignant Lymphoma (Histiocytic, Lymphocytic, Mixed, or Undifferentiated Cell Type) | | | |
| Overall rates | 7/46 (15%) | 7/49 (14%) | 8/50 (16%) |
| Adjusted rates | 21.3% | 26.7% | 27.4% |
| Terminal rates | 5/30 (17%) | 5/23 (22%) | 5/25 (20%) |
| First incidence (days) | 509 | 628 | 642 |
| Life table tests | P=0.358 | P=0.454 | P=0.387 |
| Logistic regression tests | P=0.406 | P=0.607 | P=0.463 |
| Cochran-Armitage test | P=0.514 | | |
| Fisher exact test | | P=0.563N | P=0.571 |
| All Organs: Benign Tumors | | | |
| Overall rates | 18/46 (39%) | 9/49 (18%) | 10/50 (20%) |
| Adjusted rates | 54.5% | 36.4% | 33.0% |
| Terminal rates | 15/30 (50%) | 8/23 (35%) | 6/25 (24%) |
| First incidence (days) | 683 | 559 | 548 |
| Life table tests | P=0.148N | P=0.125N | P=0.145N |
| Logistic regression tests | P=0.094N | P=0.044N | P=0.071N |
| Cochran-Armitage test | P=0.050N | | |
| Fisher exact test | | P=0.022N | P=0.033N |
| All Organs: Malignant Tumors | | | |
| Overall rates | 19/46 (41%) | 19/49 (39%) | 15/50 (30%) |
| Adjusted rates | 51.9% | 55.4% | 45.6% |
| Terminal rates | 13/30 (43%) | 9/23 (39%) | 8/25 (32%) |
| First incidence (days) | 426 | 491 | 473 |
| Life table tests | P=0.372N | P=0.340 | P=0.441N |
| Logistic regression tests | P=0.241N | P=0.546N | P=0.279N |
| Cochran-Armitage test | P=0.143N | | |
| Fisher exact test | | P=0.483N | P=0.173N |
| All Organs: Benign or Malignant Tumors | | | |
| Overall rates | 31/46 (67%) | 26/49 (53%) | 21/50 (42%) |
| Adjusted rates | 81.4% | 75.1% | 58.9% |
| Terminal rates | 23/30 (77%) | 15/23 (65%) | 11/25 (44%) |
| First incidence (days) | 426 | 491 | 473 |
| Life table tests | P=0.141N | P=0.537 | P=0.168N |
| Logistic regression tests | P=0.036N | P=0.162N | P=0.035N |
| Cochran-Armitage test | P=0.011N | | |
| Fisher exact test | | P=0.112N | P=0.011N |

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TABLE D3
Statistical Analysis of Primary Neoplasms in Female Mice in the 2-Year Inhalation Study of Talc (continued)

(T) Terminal sacrifice

^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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TABLE D4
Summary of the Incidence of Nonneoplastic Lesions in Female Mice in the 2-Year Inhalation Study of Talc^a

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|--------------------------------------|---------------------|---------------------|----------------------|
| Disposition Summary | | | |
| Animals initially in study | 50 | 50 | 50 |
| Early deaths | | | |
| Moribund | 2 | 4 | 4 |
| Natural deaths | 17 | 21 | 21 |
| Survivors | | | |
| Terminal sacrifice | 30 | 23 | 25 |
| Missing | 1 | 1 | |
| Culled | | 1 | |
| Animals examined microscopically | 46 | 48 | 50 |
| Allimentary System | | | |
| Intestine large, cecum | (35) | (29) | (34) |
| Hyperplasia, lymphoid | | | 1 (3%) |
| Serosa, inflammation, suppurative | | 1 (3%) | |
| Intestine large, colon | (38) | (33) | (32) |
| Serosa, inflammation, suppurative | | 2 (6%) | |
| Intestine small, duodenum | (27) | (25) | (27) |
| Ulcer, focal | 1 (4%) | | |
| Mucosa, atrophy | 2 (7%) | 6 (24%) | 4 (15%) |
| Serosa, inflammation, suppurative | | 2 (8%) | |
| Intestine small, ileum | (33) | (27) | (31) |
| Hyperplasia, lymphoid | 1 (3%) | 1 (4%) | |
| Mucosa, atrophy | 4 (12%) | 6 (22%) | 6 (19%) |
| Peyer's patch, necrosis | | | 1 (3%) |
| Serosa, inflammation, suppurative | | 2 (7%) | 1 (3%) |
| Intestine small, jejunum | (33) | (28) | (31) |
| Mucosa, atrophy | 2 (6%) | 7 (25%) | 3 (10%) |
| Serosa, inflammation, suppurative | | 2 (7%) | 1 (3%) |
| Liver | (46) | (46) | (50) |
| Eosinophilic focus | | 1 (2%) | |
| Fibrosis, focal | | 1 (2%) | |
| Focal cellular change | 2 (4%) | 3 (7%) | 1 (2%) |
| Hematopoietic cell proliferation | 1 (2%) | 2 (4%) | 2 (4%) |
| Inflammation, focal | 1 (2%) | 2 (4%) | 1 (2%) |
| Necrosis, focal | 1 (2%) | 2 (4%) | 2 (4%) |
| Pigmentation, hemosiderin, focal | | 1 (2%) | |
| Centrilobular, degeneration | | 1 (2%) | |
| Centrilobular, necrosis, coagulative | | 1 (2%) | |
| Serosa, inflammation, suppurative | 4 (9%) | 7 (15%) | 5 (10%) |
| Sinusoid, inflammation | 2 (4%) | | |
| Pancreas | (42) | (39) | (44) |
| Inflammation, focal | | | 2 (5%) |
| Acinus, hyperplasia, focal | 1 (2%) | | |
| Serosa, inflammation, suppurative | 1 (2%) | 5 (13%) | 4 (9%) |
| Salivary glands | (46) | (48) | (50) |
| Inflammation, acute | | 1 (2%) | 1 (2%) |
| Stomach | (45) | (45) | (50) |
| Serosa, inflammation, granulomatous | | | 1 (2%) |
| Serosa, inflammation, suppurative | 1 (2%) | 2 (4%) | 1 (2%) |
| Stomach, forestomach | (45) | (45) | (50) |
| Hyperplasia, mast cell, focal | | | 1 (2%) |
| Hyperplasia, squamous, focal | 2 (4%) | 4 (9%) | 2 (4%) |
| Ulcer, focal | 1 (2%) | 3 (7%) | |

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Lesions in Female Mice

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TABLE D4
Summary of the Incidence of Nonneoplastic Lesions in Female Mice in the 2-Year Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|--|---------------------|---------------------|----------------------|
| Allimentary System (continued) | | | |
| Stomach, glandular | (45) | (39) | (46) |
| Inflammation, suppurative | | | 1 (2%) |
| Ulcer, focal | 1 (2%) | 1 (3%) | |
| Forestomach, inflammation, focal | | 1 (3%) | 2 (4%) |
| Cardiovascular System | | | |
| Heart | (46) | (48) | (50) |
| Myocardium, degeneration, focal | 1 (2%) | | |
| Myocardium, inflammation, focal | | 1 (2%) | |
| Myocardium, mineralization, focal | 1 (2%) | | |
| Pericardium, inflammation, suppurative | 1 (2%) | 2 (4%) | 4 (8%) |
| Endocrine System | | | |
| Adrenal gland | (46) | (45) | (50) |
| Capsule, inflammation, suppurative | 4 (9%) | 7 (16%) | 5 (10%) |
| Corticomedullary junction, hemorrhage | 2 (4%) | 3 (7%) | 1 (2%) |
| Spindle cell, hyperplasia | 46 (100%) | 45 (100%) | 47 (94%) |
| Adrenal gland, cortex | (46) | (44) | (50) |
| Cyst | 2 (4%) | 3 (7%) | |
| Inflammation, suppurative, focal | | | 1 (2%) |
| Vacuolization cytoplasmic, focal | 3 (7%) | | |
| Adrenal gland, medulla | (41) | (43) | (45) |
| Hyperplasia, focal | 2 (5%) | | |
| Parathyroid gland | (23) | (18) | (25) |
| Hyperplasia | 1 (4%) | | |
| Pituitary gland | (42) | (42) | (48) |
| Cyst | 2 (5%) | | |
| Hemorrhage, focal | 2 (5%) | | |
| Hyperplasia, focal | 2 (5%) | | |
| Pigmentation, lipofuscin | 1 (2%) | | |
| Thyroid gland | (43) | (47) | (49) |
| Cyst | 2 (5%) | | |
| Inflammation, acute, focal | | | 2 (4%) |
| C-cell, hyperplasia | 1 (2%) | | 1 (2%) |
| Follicular cell, hyperplasia | 9 (21%) | 12 (26%) | 10 (20%) |
| General Body System | | | |
| Tissue NOS | (4) | (1) | (2) |
| Thrombosis, chronic | 1 (25%) | | |
| Genital System | | | |
| Ovary | (38) | (43) | (46) |
| Abscess | 4 (11%) | 10 (23%) | 7 (15%) |
| Cyst | 6 (16%) | 11 (26%) | 10 (22%) |
| Thrombosis | 1 (3%) | 2 (5%) | |
| Uterus | (44) | (45) | (49) |
| Angiectasis | | | 1 (2%) |
| Hyperplasia, histiocytic, focal | | | 1 (2%) |
| Metaplasia, squamous | | 1 (2%) | |
| Thrombosis | 1 (2%) | | |
| Endometrium, hyperplasia, cystic | 34 (77%) | 30 (67%) | 35 (71%) |
| Mucosa, inflammation, suppurative | 3 (7%) | 7 (16%) | 4 (8%) |
| Serosa, inflammation, suppurative | 1 (2%) | 4 (9%) | 2 (4%) |

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Talc, NTP TR 421

TABLE D4
Summary of the Incidence of Nonneoplastic Lesions in Female Mice in the 2-Year Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|---|---------------------|---------------------|----------------------|
| Hematopoietic System | | | |
| Bone marrow | (41) | (43) | (45) |
| Hyperplasia | 1 (2%) | 4 (9%) | 5 (11%) |
| Myelofibrosis | 28 (68%) | 23 (53%) | 27 (60%) |
| Myeloid cell, hyperplasia | 1 (2%) | 6 (14%) | 3 (7%) |
| Lymph node | (46) | (46) | (49) |
| Iliac, hyperplasia, lymphoid | | | 1 (2%) |
| Iliac, inflammation | 1 (2%) | | 1 (2%) |
| Pancreatic, hyperplasia, lymphoid | 1 (2%) | | 1 (2%) |
| Pancreatic, infiltration cellular, mixed cell | | | 1 (2%) |
| Pancreatic, follicular, necrosis | | | 1 (2%) |
| Renal, hyperplasia, lymphoid | | 2 (4%) | 2 (4%) |
| Renal, infiltration cellular, mixed cell | | | 1 (2%) |
| Renal, inflammation | 1 (2%) | 1 (2%) | 1 (2%) |
| Renal, follicular, necrosis | | 2 (4%) | 1 (2%) |
| Lymph node, bronchial | (38) | (37) | (43) |
| Hyperplasia, histiocytic | | 25 (68%) | 39 (91%) |
| Hyperplasia, lymphoid | | 16 (43%) | 20 (47%) |
| Infiltration cellular, mixed cell | 1 (3%) | | |
| Inflammation, acute | 1 (3%) | 1 (3%) | 1 (2%) |
| Lymph node, mandibular | (35) | (38) | (36) |
| Cyst | | | 1 (3%) |
| Depletion lymphoid | 1 (3%) | | |
| Hyperplasia, histiocytic | 1 (3%) | | |
| Hyperplasia, lymphoid | | 1 (3%) | 3 (8%) |
| Hyperplasia, plasma cell | 1 (3%) | | |
| Infiltration cellular, mixed cell | | 1 (3%) | |
| Inflammation | | 1 (3%) | 1 (3%) |
| Follicular, necrosis | | 1 (3%) | |
| Lymph node, mediastinal | (13) | (17) | (14) |
| Hyperplasia, histiocytic | 1 (8%) | 3 (18%) | 2 (14%) |
| Hyperplasia, lymphoid | | 1 (6%) | 2 (14%) |
| Infiltration cellular, mixed cell | 1 (8%) | | |
| Lymph node, mesenteric | (35) | (31) | (37) |
| Depletion lymphoid | | 1 (3%) | 2 (5%) |
| Hematocyst | | | 1 (3%) |
| Hyperplasia, histiocytic | | 1 (3%) | 1 (3%) |
| Hyperplasia, lymphoid | | 2 (6%) | 2 (5%) |
| Hyperplasia, plasma cell | | | 1 (3%) |
| Infiltration cellular, mixed cell | 5 (14%) | 5 (16%) | 5 (14%) |
| Inflammation | | 2 (6%) | 1 (3%) |
| Follicular, necrosis | 3 (9%) | 12 (39%) | 7 (19%) |
| Spleen | (45) | (44) | (50) |
| Congestion | 2 (4%) | | |
| Hematopoietic cell proliferation | 8 (18%) | 12 (27%) | 10 (20%) |
| Hyperplasia, lymphoid | 5 (11%) | 8 (18%) | 6 (12%) |
| Inflammation, suppurative | 2 (4%) | | 1 (2%) |
| Capsule, inflammation, suppurative | 2 (4%) | 3 (7%) | 3 (6%) |
| Lymphoid follicle, depletion lymphoid | 2 (4%) | 3 (7%) | 5 (10%) |
| Lymphoid follicle, necrosis | 2 (4%) | 4 (9%) | 2 (4%) |
| Thymus | (40) | (40) | (41) |
| Cyst | 2 (5%) | 2 (5%) | |
| Hyperplasia, plasma cell | | 1 (3%) | |
| Inflammation, suppurative | | 1 (3%) | 1 (2%) |
| Necrosis | 3 (8%) | 5 (13%) | |
| Cortex, depletion lymphoid | 8 (20%) | 12 (30%) | 15 (37%) |

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Lesions in Female Mice

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TABLE D4
Summary of the Incidence of Nonneoplastic Lesions in Female Mice in the 2-Year Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|--|---------------------|---------------------|----------------------|
| Integumentary System | | | |
| Mammary gland | (41) | (45) | (48) |
| Abscess | | | 1 (2%) |
| Edema | 1 (2%) | | |
| Skin | (46) | (46) | (50) |
| Alopecia | 2 (4%) | 2 (4%) | |
| Musculoskeletal System | | | |
| Bone | (46) | (48) | (50) |
| Periosteum, femur, proliferation connective tissue | 1 (2%) | | |
| Nervous System | | | |
| Brain | (46) | (48) | (50) |
| Hydrocephalus | | 2 (4%) | |
| Mineralization, focal | 36 (78%) | 33 (69%) | 29 (58%) |
| Respiratory System | | | |
| Larynx | (42) | (43) | (48) |
| Inflammation, acute | 1 (2%) | | |
| Lung | (46) | (48) | (50) |
| Congestion | 1 (2%) | 3 (6%) | |
| Hyperplasia, histiocytic | | | 1 (2%) |
| Hyperplasia, macrophage | 2 (4%) | 45 (94%) | 43 (86%) |
| Inflammation, chronic active | | 25 (52%) | 38 (76%) |
| Metaplasia, osseous, focal | 1 (2%) | | |
| Alveolar epithelium, hyperplasia, focal | | | 1 (2%) |
| Perivascular, inflammation, suppurative | | 3 (6%) | 1 (2%) |
| Pleura, inflammation, suppurative | 1 (2%) | 2 (4%) | 5 (10%) |
| Nose | (46) | (46) | (50) |
| Cytoplasmic alteration, focal | 29 (63%) | 37 (80%) | 40 (80%) |
| Developmental malformation | 1 (2%) | | |
| Erosion, focal | 3 (7%) | | 1 (2%) |
| Inflammation, acute | 6 (13%) | 4 (9%) | 5 (10%) |
| Ulcer, focal | 1 (2%) | | |
| Special Senses System | | | |
| Eye | | (1) | |
| Inflammation, suppurative | | 1 (100%) | |
| Harderian gland | (2) | (2) | (1) |
| Inflammation, suppurative | | 1 (50%) | |
| Urinary System | | | |
| Kidney | (46) | (46) | (50) |
| Casts protein | | 2 (4%) | |
| Infarct | 1 (2%) | 1 (2%) | |
| Inflammation, focal | 1 (2%) | 1 (2%) | 1 (2%) |
| Metaplasia, osseous, focal | 1 (2%) | | 2 (4%) |
| Nephropathy, chronic | 1 (2%) | 1 (2%) | |
| Capsule, inflammation, suppurative | 3 (7%) | 6 (13%) | 5 (10%) |
| Renal tubule, hyperplasia, focal | | 1 (2%) | |

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TABLE D4
Summary of the Incidence of Nonneoplastic Lesions in Female Mice in the 2-Year Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|--------------------------------------|---------------------|---------------------|----------------------|
| Urinary System (continued) | | | |
| Urinary bladder | (44) | (40) | (41) |
| Serosa, inflammation, suppurative | | 3 (8%) | 3 (7%) |
| Submucosa, hyperplasia, lymphoid | 1 (2%) | | |
| Submucosa, inflammation, suppurative | | | 1 (2%) |

^a Incidences are expressed as the ratio of animals with lesions to the number of animals examined microscopically at the site.

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APPENDIX E ORGAN WEIGHTS AND ORGAN-WEIGHT-TO-BODY-WEIGHT RATIOS

| | | |
|----------|---|------|
| TABLE E1 | Organ Weights and Organ-Weight-to-Body-Weight Ratios for Rats at the 6-Month Interim Evaluation in the Lifetime Inhalation Study of Talc | E-2 |
| TABLE E2 | Organ Weights and Organ-Weight-to-Body-Weight Ratios for Rats at the 11-Month Interim Evaluation in the Lifetime Inhalation Study of Talc | E-3 |
| TABLE E3 | Organ Weights and Organ-Weight-to-Body-Weight Ratios for Rats at the 18-Month Interim Evaluation in the Lifetime Inhalation Study of Talc | E-4 |
| TABLE E4 | Organ Weights and Organ-Weight-to-Body-Weight Ratios for Rats at the 24-Month Interim Evaluation in the Lifetime Inhalation Study of Talc | E-5 |
| TABLE E5 | Organ Weights and Organ-Weight-to-Body-Weight Ratios for Rats at the Termination of the Lifetime Inhalation Study of Talc | E-6 |
| TABLE E6 | Organ Weights and Organ-Weight-to-Body-Weight Ratios for Mice at the 6-Month Interim Evaluation in the 2-Year Inhalation Study of Talc | E-7 |
| TABLE E7 | Organ Weights and Organ-Weight-to-Body-Weight Ratios for Mice at the 12-Month Interim Evaluation in the 2-Year Inhalation Study of Talc | E-8 |
| TABLE E8 | Organ Weights and Organ-Weight-to-Body-Weight Ratios for Mice at the 18-Month Interim Evaluation in the 2-Year Inhalation Study of Talc | E-9 |
| TABLE E9 | Organ Weights and Organ-Weight-to-Body-Weight Ratios for Mice at the Termination of the 2-Year Inhalation Study of Talc | E-10 |

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TABLE E1
Organ Weights and Organ-Weight-to-Body-Weight Ratios for Rats at the 6-Month Interim Evaluation
in the Lifetime Inhalation Study of Talc^a

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|------------------|---------------------|---------------------|----------------------|
| Male | | | |
| n | 3 | 3 | 3 |
| Necropsy body wt | 379 ± 2 | 365 ± 9 | 351 ± 4* |
| Brain | | | |
| Absolute | 2.061 ± 0.073 | 1.962 ± 0.035 | 1.964 ± 0.041 |
| Relative | 5.44 ± 0.22 | 5.38 ± 0.22 | 5.59 ± 0.10 |
| Heart | | | |
| Absolute | 1.087 ± 0.024 | 0.984 ± 0.047 | 1.008 ± 0.018 |
| Relative | 2.87 ± 0.07 | 2.69 ± 0.07 | 2.87 ± 0.03 |
| R. Kidney | | | |
| Absolute | 1.203 ± 0.055 | 1.155 ± 0.028 | 1.143 ± 0.025 |
| Relative | 3.17 ± 0.16 | 3.16 ± 0.01 | 3.25 ± 0.04 |
| Liver | | | |
| Absolute | 12.969 ± 0.336 | 11.658 ± 0.483 | 11.644 ± 0.613 |
| Relative | 34.20 ± 0.79 | 31.89 ± 0.65 | 33.11 ± 1.43 |
| Lungs | | | |
| Absolute | 1.196 ± 0.049 | 1.201 ± 0.060 | 1.600 ± 0.073** |
| Relative | 3.15 ± 0.11 | 3.29 ± 0.19 | 4.55 ± 0.19** |
| Female | | | |
| n | 3 | 3 | 3 |
| Necropsy body wt | 216 ± 10 | 210 ± 5 | 212 ± 7 |
| Brain | | | |
| Absolute | 1.801 ± 0.020 | 1.800 ± 0.030 | 1.860 ± 0.031 |
| Relative | 8.39 ± 0.33 | 8.57 ± 0.28 | 8.82 ± 0.39 |
| Heart | | | |
| Absolute | 0.679 ± 0.023 | 0.691 ± 0.031 | 0.716 ± 0.055 |
| Relative | 3.16 ± 0.11 | 3.29 ± 0.13 | 3.38 ± 0.20 |
| R. Kidney | | | |
| Absolute | 0.700 ± 0.043 | 0.775 ± 0.025 | 0.751 ± 0.030 |
| Relative | 3.25 ± 0.17 | 3.69 ± 0.10 | 3.55 ± 0.07 |
| Liver | | | |
| Absolute | 7.579 ± 0.502 | 7.253 ± 0.172 | 6.875 ± 0.409 |
| Relative | 35.13 ± 1.09 | 34.51 ± 0.33 | 32.47 ± 1.21 |
| Lungs | | | |
| Absolute | 1.006 ± 0.112 | 0.986 ± 0.064 | 1.090 ± 0.010 |
| Relative | 4.71 ± 0.65 | 4.69 ± 0.29 | 5.17 ± 0.21 |

* Significantly different (P≤0.05) from the control group by Williams' or Dunnett's test

** P≤0.01

^a Organ weights and body weights are given in grams; organ-weight-to-body-weight ratios are given as mg organ weight/g body weight (mean ± standard error)

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