

C-14

Talc, NTP TR 421

**TABLE C2
Individual Animal Tumor Pathology of Male Mice in the 2-Year Inhalation Study of Talc: 6 mg/m³ (continued)**

| | |
|---|---|
| Number of Days on Study | 2 2 3 4 5 5 5 5 5 5 6 6 6 6 6 7 7 7 7 7 7 |
| | 5 5 4 2 4 5 5 8 9 9 2 2 3 8 8 8 1 1 2 3 3 3 3 |
| | 3 3 4 3 6 0 8 4 0 1 4 6 3 1 5 8 0 9 2 6 6 6 6 |
| Carcass ID Number | 0 1 0 0 1 1 0 1 1 1 0 0 0 1 1 0 0 1 1 0 0 0 0 |
| | 3 3 4 0 2 6 4 5 5 2 4 7 3 5 0 6 1 5 3 0 0 0 0 |
| | 5 3 2 7 1 4 0 1 6 9 1 4 8 7 0 1 5 4 2 1 4 5 8 |
| | 1 |
| General Body System | |
| Tissue NOS | + + + |
| Genital System | |
| Epididymis | A + + + + + + + + + + + + A + + + + + + + + |
| Preputial gland | + |
| Prostate | + + M A I A + + + + + + + + + + + + + + + + |
| Seminal vesicle | A + + A + A + + + + + + + + A + + + + + + + + |
| Testes | A + + + + A + + + + + + + + A + + + + + + + + |
| Hematopoietic System | |
| Bone marrow | + + + + A A + A A A + + + + + + + + + + + + |
| Lymph node | + M + |
| Lymph node, bronchial | + + + + M + I + + + + + + + + M + + + + + M + |
| Lymph node, mandibular | M M + M M + + + + M + M M 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 M |
| Lymph node, mesenteric | M M M M + M + + + + + M + + + M + + + M + |
| Spleen | A + + + + A A + + + + + + + + + + + + + + |
| Thymus | A M M M + + + I + + M + M + I M + + + + + + + |
| Integumentary System | |
| Mammary gland | M M M M M A M M M M M M M M + M + + M + M M |
| Skin | + |
| Musculoskeletal System | |
| Bone | + |
| Nervous System | |
| Brain | + |
| Respiratory System | |
| Larynx | A + + A + A A + + + + + A + + + + + + + I + + |
| Lung | + |
| Alveolar/bronchiolar adenoma | |
| Alveolar/bronchiolar carcinoma | X |
| Hepatocellular carcinoma, metastatic, liver | |
| | X |
| Nose | + + + + + A + + + + + + + + + + + + + + + + |
| Trachea | + + + + + A I + + + + + A + + + + + + + + + + |

NOT FOR DISTRIBUTION OR ATTRIBUTION

Board Draft

Lesions in Male Mice

C-15

TABLE C2
Individual Animal Tumor Pathology of Male Mice in the 2-Year Inhalation Study of Talc: 6 mg/m³ (continued)

| | | |
|---|---|-----------------------------|
| Number of Days on Study | 7 | |
| | 3 | |
| | 6 6 7 7 7 7 7 7 7 7 8 8 8 8 8 8 9 9 9 9 0 0 0 0 0 0 | |
| Carcass ID Number | 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 0 0 1 1 1 1 | Total Tissues/ Tumors |
| | 1 1 3 3 6 6 6 7 7 9 9 9 9 9 0 0 2 3 5 3 9 2 2 5 6 | |
| | 0 4 3 6 4 5 6 1 2 3 5 6 9 1 5 7 5 5 2 2 4 5 8 2 | |
| | 1 | |
| General Body System | | |
| Tissue NOS | | 3 |
| Genital System | | |
| Epididymis | M + + + + + M + + + + I + + + + I I + + + I + | 39 |
| Preputial gland | | 6 |
| Prostate | + | 43 |
| Seminal vesicle | + | 43 |
| Testes | + | 44 |
| Hematopoietic System | | |
| Bone marrow | + | 42 |
| Lymph node | + | 46 |
| Lymph node, bronchial | + + + + M + + + + + + + + M + + + M + + + + + M | 39 |
| Lymph node, mandibular | + M + + M + M M M + M + M + + + M M + M + + M M | 23 |
| Lymph node, mediastinal | M M M + M M + M M M M + M M + M M M + M M M M + | 10 |
| Lymph node, mesenteric | + | 39 |
| Spleen | + | 44 |
| Thymus | + + + + I + + + M + I + + + + M + + + + + + + + I | 33 |
| Integumentary System | | |
| Mammary gland | M M M M M M M M M M M M M M M M M + M M M M M | 5 |
| Skin | + I + + + + + + + + + + + + + + + + + + M + + + + + | 45 |
| Musculoskeletal System | | |
| Bone | + | 47 |
| Nervous System | | |
| Brain | + | 47 |
| Respiratory System | | |
| Larynx | + | 41 |
| Lung | + | 47 |
| Alveolar/bronchiolar adenoma | X | 4 |
| Alveolar/bronchiolar carcinoma | | 2 |
| Hepatocellular carcinoma, metastatic, liver | | 1 |
| Nose | + | 46 |
| Trachea | + + + + + + + + + + + + + + M + + + + + + + + + + + + | 43 |

Board Draft

NOT FOR DISTRIBUTION OR ATTRIBUTION

C-16

Talc, NTP TR 421

TABLE C2
Individual Animal Tumor Pathology of Male Mice in the 2-Year Inhalation Study of Talc: 6 mg/m³ (continued)

| | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Number of Days on Study | 2 | 2 | 3 | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| | 5 | 5 | 4 | 2 | 4 | 5 | 5 | 8 | 9 | 9 | 2 | 2 | 3 | 8 | 8 | 8 | 1 | 1 | 2 | 3 | 3 | 3 | 3 |
| | 3 | 3 | 4 | 3 | 6 | 0 | 8 | 4 | 0 | 1 | 4 | 6 | 3 | 1 | 5 | 8 | 0 | 9 | 2 | 6 | 6 | 6 | 6 |
| Carcass ID Number | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 4 | 0 | 2 | 6 | 4 | 5 | 5 | 2 | 4 | 7 | 3 | 5 | 0 | 6 | 1 | 5 | 3 | 0 | 0 | 0 | 0 |
| | 5 | 3 | 2 | 7 | 1 | 4 | 0 | 1 | 6 | 9 | 1 | 4 | 8 | 7 | 0 | 1 | 5 | 4 | 2 | 1 | 4 | 5 | 8 |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Special Senses System | | | | | | | | | | | | | | | | | | | | | | | |
| None | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary System | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Urinary bladder | A | + | + | A | + | A | A | A | + | + | + | + | A | + | A | + | A | + | + | + | + | + | + |
| Systemic Lesions | | | | | | | | | | | | | | | | | | | | | | | |
| Multiple organs | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Lymphoma malignant lymphocytic | | | | | | | | | | | | | | | | | | | | | | X | |

NOT FOR DISTRIBUTION OR ATTRIBUTION

Board Draft

Lesions in Male Mice

C-17

TABLE C2
Individual Animal Tumor Pathology of Male Mice in the 2-Year Inhalation Study of Talc: 6 mg/m³ (continued)

| | | |
|--------------------------------|---|--------------------------------------|
| Number of Days on Study | 7 | |
| | 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 | |
| | 6 6 7 7 7 7 7 7 7 8 8 8 8 8 8 9 9 9 0 0 0 0 0 | |
| Carcass ID Number | 0 0 0 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 0 0 1 1 1 1 | Total Tissues/ Tumors |
| | 1 1 3 3 6 6 6 7 7 9 9 9 9 0 0 2 3 5 3 9 2 2 5 6 | |
| | 0 4 3 6 4 5 6 1 2 3 5 6 9 1 5 7 5 5 2 2 4 5 8 2 | |
| Special Senses System | | |
| None | | |
| Urinary System | | |
| Kidney | + | 46 |
| Urinary bladder | + + + + + + + + + + + + + + + + + M + + + + | 38 |
| Systemic Lesions | | |
| Multiple organs | + | 47 |
| Lymphoma malignant lymphocytic | | 1 |

C-20

Talc, NTP TR 421

TABLE C2
Individual Animal Tumor Pathology of Male Mice in the 2-Year Inhalation Study of Talc: 18 mg/m³ (continued)

| | |
|--|---|
| Number of Days on Study | 0 1 1 1 4 4 4 4 5 5 5 6 6 7 7 7 7 7 7 7 7 7 7 |
| | 2 1 1 5 2 3 5 7 3 4 5 5 7 2 2 2 2 3 3 3 3 3 3 3 |
| | 8 4 5 9 2 8 7 8 8 1 4 8 2 1 4 5 7 6 6 6 6 6 6 6 |
| Carcass ID Number | 1 1 1 3 2 1 2 2 1 2 2 2 2 2 3 3 1 1 1 1 2 2 2 |
| | 8 8 9 1 8 8 2 1 8 7 4 8 4 8 1 0 4 8 8 9 9 1 1 1 |
| | 7 3 5 0 5 6 1 9 5 7 9 3 1 2 5 6 3 4 9 2 3 1 3 4 |
| | 1 |
| Genital System | |
| Epididymis | + + + + A + + + + M + + A + + + + + M + + + |
| Preputial gland | + + + + |
| Prostate | + M M M A + + + + A + + + + + + + + + + + |
| Seminal vesicle | + M M M A + + + + A A A M A + + + + + + + + + |
| Testes | + + + + A + + + + A M + A + + + + + + + + + |
| Hematopoietic System | |
| Bone marrow | + + + + A A + + A A A A + + + + + + + + + + + |
| Lymph node | + + + + + + + + + M + + + + + + + + + + + |
| Lymph node, bronchial | + + M M A + + + + M + + + + + + + + + + + |
| Alveolar/bronchiolar carcinoma, metastatic, lung | X |
| Lymph node, mandibular | M I I + A M + M + M M M M + + + + + M M M M |
| Hemangiosarcoma, metastatic, spleen | X |
| Lymph node, mediastinal | M M M M M M M M M M M + M + M M + M M M M M |
| Lymph node, mesenteric | M + + M A + + M + + A + + A + + M + + + + + + + |
| Hemangiosarcoma, metastatic, spleen | X |
| Spleen | + + + + A + + + + A + + + + + + + + + + + |
| Hemangiosarcoma | X X |
| Thymus | + M + M M + + + + A + M + + + + + + + M + + + |
| Alveolar/bronchiolar carcinoma, metastatic, lung | X |
| Integumentary System | |
| Mammary gland | I I M M M M M + + M M M M M M M M M M M M M |
| Skin | + + + + + + + + + + + + + + + I + + + + + + + + + |
| Musculoskeletal System | |
| Bone | + |
| Hemangiosarcoma, metastatic, spleen | X |
| Skeletal muscle | + |
| Thoracic, alveolar/bronchiolar carcinoma, metastatic, lung | X |
| Nervous System | |
| Brain | + + + + A + + + + + + + + + + + + + + + + + |

NOT FOR DISTRIBUTION OR ATTRIBUTION

Board Draft

Lesions in Male Mice

C-23

TABLE C2
Individual Animal Tumor Pathology of Male Mice in the 2-Year Inhalation Study of Talc: 18 mg/m³ (continued)

| | | |
|---|---|-----------------------------|
| Number of Days on Study | 7 | |
| | 3 | |
| | 7 7 7 7 7 7 7 8 8 8 8 8 9 9 9 9 9 9 9 0 0 0 0 0 0 | |
| Carcass ID Number | 2 2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 2 2 2 3 3 3 | |
| | 2 2 4 4 5 5 5 7 8 0 0 0 3 3 3 3 3 3 3 4 1 5 5 0 1 1 | |
| | 3 4 2 8 0 1 2 9 4 3 4 8 2 3 4 7 8 9 5 7 3 5 7 1 3 | |
| | 1 | Total Tissues/Tumors |
| Respiratory System | | |
| Larynx | + | 46 |
| Lung | + | 48 |
| Alveolar/bronchiolar adenoma | | 7 |
| Alveolar/bronchiolar adenoma, multiple | X | 2 |
| Alveolar/bronchiolar carcinoma | | 2 |
| Hemangiosarcoma, metastatic, spleen | | 1 |
| Hepatocellular carcinoma, metastatic, liver | | 2 |
| Nose | + | 47 |
| Trachea | + + + + + 1 + + M + + + + + + + + + + + + + + + + + + | 42 |
| Special Senses System | | |
| Harderian gland | + + | 4 |
| Adenoma | X X | 4 |
| Urinary System | | |
| Kidney | + | 48 |
| Urinary bladder | + | 43 |
| Systemic Lesions | | |
| Multiple organs | + | 49 |

C-24

Talc, NTP TR 421

TABLE C3
Statistical Analysis of Primary Neoplasms in Male Mice in the 2-Year Inhalation Study of Talc

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|---|---------------------|---------------------|----------------------|
| Harderian Gland: Adenoma | | | |
| Overall rates ^a | 1/46 (2%) | 0/47 (0%) | 4/49 (8%) |
| Adjusted rates ^b | 3.3% | 0.0% | 12.0% |
| Terminal rates ^c | 1/30 (3%) | 0/28 (0%) | 3/32 (9%) |
| First incidence (days) | 736 (T) | - ^e | 725 |
| Life table tests ^d | P=0.073 | P=0.514N | P=0.204 |
| Logistic regression tests ^d | P=0.075 | P=0.514N | P=0.216 |
| Cochran-Armitage test ^d | P=0.065 | | |
| Fisher exact test ^d | | P=0.495N | P=0.201 |
| Liver: Hepatocellular Adenoma | | | |
| Overall rates | 3/45 (7%) | 9/47 (19%) | 4/48 (8%) |
| Adjusted rates | 10.0% | 29.5% | 11.8% |
| Terminal rates | 3/30 (10%) | 7/28 (25%) | 3/32 (9%) |
| First incidence (days) | 736 (T) | 633 | 672 |
| Life table tests | P=0.489N | P=0.050 | P=0.539 |
| Logistic regression tests | P=0.493N | P=0.061 | P=0.552 |
| Cochran-Armitage test | P=0.515N | | |
| Fisher exact test | | P=0.070 | P=0.536 |
| Liver: Hepatocellular Carcinoma | | | |
| Overall rates | 6/45 (13%) | 5/47 (11%) | 11/48 (23%) |
| Adjusted rates | 16.7% | 13.7% | 27.3% |
| Terminal rates | 2/30 (7%) | 1/28 (4%) | 5/32 (16%) |
| First incidence (days) | 571 | 546 | 438 |
| Life table tests | P=0.114 | P=0.491N | P=0.187 |
| Logistic regression tests | P=0.116 | P=0.445N | P=0.203 |
| Cochran-Armitage test | P=0.097 | | |
| Fisher exact test | | P=0.469N | P=0.177 |
| Liver: Hepatocellular Adenoma or Carcinoma | | | |
| Overall rates | 9/45 (20%) | 13/47 (28%) | 14/48 (29%) |
| Adjusted rates | 25.6% | 38.1% | 34.5% |
| Terminal rates | 5/30 (17%) | 8/28 (29%) | 7/32 (22%) |
| First incidence (days) | 571 | 546 | 438 |
| Life table tests | P=0.256 | P=0.228 | P=0.230 |
| Logistic regression tests | P=0.216 | P=0.257 | P=0.223 |
| Cochran-Armitage test | P=0.225 | | |
| Fisher exact test | | P=0.269 | P=0.217 |
| Lung: Alveolar/bronchiolar Adenoma | | | |
| Overall rates | 6/45 (13%) | 4/47 (9%) | 9/48 (19%) |
| Adjusted rates | 20.0% | 14.3% | 27.0% |
| Terminal rates | 6/30 (20%) | 4/28 (14%) | 8/32 (25%) |
| First incidence (days) | 736 (T) | 736 (T) | 672 |
| Life table tests | P=0.224 | P=0.411N | P=0.333 |
| Logistic regression tests | P=0.251 | P=0.411N | P=0.371 |
| Cochran-Armitage test | P=0.210 | | |
| Fisher exact test | | P=0.342N | P=0.336 |

NOT FOR DISTRIBUTION OR ATTRIBUTION

Board Draft

Lesions in Male Mice

C-25

TABLE C3
Statistical Analysis of Primary Neoplasms in Male 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 Carcinoma | | | |
| Overall rates | 7/45 (16%) | 2/47 (4%) | 2/48 (4%) |
| Adjusted rates | 23.3% | 5.9% | 5.2% |
| Terminal rates | 7/30 (23%) | 1/28 (4%) | 0/32 (0%) |
| First incidence (days) | 736 (T) | 558 | 438 |
| Life table tests | P=0.068N | P=0.093N | P=0.068N |
| Logistic regression tests | P=0.069N | P=0.073N | P=0.070N |
| Cochran-Armitage test | P=0.065N | | |
| Fisher exact test | | P=0.069N | P=0.065N |
| Lung: Alveolar/bronchiolar Adenoma or Carcinoma | | | |
| Overall rates | 12/45 (27%) | 5/47 (11%) | 11/48 (23%) |
| Adjusted rates | 40.0% | 16.4% | 30.8% |
| Terminal rates | 12/30 (40%) | 4/28 (14%) | 8/32 (25%) |
| First incidence (days) | 736 (T) | 558 | 438 |
| Life table tests | P=0.533N | P=0.063N | P=0.426N |
| Logistic regression tests | P=0.552N | P=0.043N | P=0.423N |
| Cochran-Armitage test | P=0.554N | | |
| Fisher exact test | | P=0.043N | P=0.429N |
| Pituitary Gland (Pars Intermedia): Adenoma | | | |
| Overall rates | 0/44 (0%) | 2/44 (5%) | 0/46 (0%) |
| Adjusted rates | 0.0% | 6.5% | 0.0% |
| Terminal rates | 0/29 (0%) | 1/27 (4%) | 0/32 (0%) |
| First incidence (days) | - | 681 | - |
| Life table tests | P=0.547N | P=0.238 | - |
| Logistic regression tests | P=0.566N | P=0.239 | - |
| Cochran-Armitage test | P=0.564N | | |
| Fisher exact test | | P=0.247 | - |
| Spleen: Hemangiosarcoma | | | |
| Overall rates | 2/44 (5%) | 0/44 (0%) | 2/47 (4%) |
| Adjusted rates | 6.9% | 0.0% | 5.5% |
| Terminal rates | 2/29 (7%) | 0/28 (0%) | 0/32 (0%) |
| First incidence (days) | 736 (T) | - | 672 |
| Life table tests | P=0.595 | P=0.246N | P=0.650N |
| Logistic regression tests | P=0.581 | P=0.246N | P=0.668N |
| Cochran-Armitage test | P=0.577 | | |
| Fisher exact test | | P=0.247N | P=0.666N |
| All Organs: Hemangiosarcoma | | | |
| Overall rates | 4/46 (9%) | 0/47 (0%) | 3/49 (6%) |
| Adjusted rates | 12.9% | 0.0% | 8.4% |
| Terminal rates | 3/30 (10%) | 0/28 (0%) | 1/32 (3%) |
| First incidence (days) | 710 | - | 672 |
| Life table tests | P=0.529N | P=0.071N | P=0.448N |
| Logistic regression tests | P=0.545N | P=0.060N | P=0.456N |
| Cochran-Armitage test | P=0.554N | | |
| Fisher exact test | | P=0.056N | P=0.464N |

Board Draft

NOT FOR DISTRIBUTION OR ATTRIBUTION

C-26

Talc, NTP TR 421

TABLE C3
Statistical Analysis of Primary Neoplasms in Male 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 | 4/46 (9%) | 0/47 (0%) | 4/49 (8%) |
| Adjusted rates | 12.9% | 0.0% | 11.4% |
| Terminal rates | 3/30 (10%) | 0/28 (0%) | 2/32 (6%) |
| First incidence (days) | 710 | - | 672 |
| Life table tests | P=0.515 | P=0.071N | P=0.590N |
| Logistic regression tests | P=0.505 | P=0.060N | P=0.598N |
| Cochran-Armitage test | P=0.492 | | |
| Fisher exact test | | P=0.056N | P=0.607N |
| All Organs: Malignant Lymphoma (Lymphocytic, Mixed, or Undifferentiated Cell Type) | | | |
| Overall rates | 5/46 (11%) | 1/47 (2%) | 0/49 (0%) |
| Adjusted rates | 16.7% | 3.6% | 0.0% |
| Terminal rates | 5/30 (17%) | 1/28 (4%) | 0/32 (0%) |
| First incidence (days) | 736 (T) | 736 (T) | - |
| Life table tests | P=0.019N | P=0.116N | P=0.027N |
| Logistic regression tests | P=0.019N | P=0.116N | P=0.027N |
| Cochran-Armitage test | P=0.020N | | |
| Fisher exact test | | P=0.097N | P=0.024N |
| All Organs: Benign Tumors | | | |
| Overall rates | 11/46 (24%) | 16/47 (34%) | 18/49 (37%) |
| Adjusted rates | 35.2% | 51.1% | 51.4% |
| Terminal rates | 10/30 (33%) | 13/28 (46%) | 15/32 (47%) |
| First incidence (days) | 587 | 633 | 672 |
| Life table tests | P=0.158 | P=0.135 | P=0.127 |
| Logistic regression tests | P=0.154 | P=0.188 | P=0.138 |
| Cochran-Armitage test | P=0.139 | | |
| Fisher exact test | | P=0.199 | P=0.128 |
| All Organs: Malignant Tumors | | | |
| Overall rates | 20/46 (43%) | 8/47 (17%) | 15/49 (31%) |
| Adjusted rates | 58.3% | 23.3% | 35.9% |
| Terminal rates | 16/30 (53%) | 4/28 (14%) | 6/32 (19%) |
| First incidence (days) | 571 | 546 | 438 |
| Life table tests | P=0.253N | P=0.012N | P=0.166N |
| Logistic regression tests | P=0.262N | P=0.005N | P=0.152N |
| Cochran-Armitage test | P=0.245N | | |
| Fisher exact test | | P=0.005N | P=0.139N |
| All Organs: Benign or Malignant Tumors | | | |
| Overall rates | 26/46 (57%) | 20/47 (43%) | 28/49 (57%) |
| Adjusted rates | 76.2% | 58.0% | 66.5% |
| Terminal rates | 22/30 (73%) | 14/28 (50%) | 18/32 (56%) |
| First incidence (days) | 571 | 546 | 438 |
| Life table tests | P=0.442 | P=0.208N | P=0.554 |
| Logistic regression tests | P=0.344 | P=0.102N | P=0.503 |
| Cochran-Armitage test | P=0.399 | | |
| Fisher exact test | | P=0.127N | P=0.558 |

NOT FOR DISTRIBUTION OR ATTRIBUTION

Board Draft

Lesions in Male Mice

C-27

TABLE C3
Statistical Analysis of Primary Neoplasms in Male 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.

Board Draft

NOT FOR DISTRIBUTION OR ATTRIBUTION

C-28

Talc, NTP TR 421

TABLE C4
Summary of the Incidence of Nonneoplastic Lesions in Male 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 | 1 | 2 | 3 |
| Natural deaths | 16 | 18 | 14 |
| Survivors | | | |
| Terminal sacrifice | 30 | 28 | 32 |
| Missexed | 1 | 1 | 0 |
| Missing | 2 | 1 | 1 |
| Animals examined microscopically | 46 | 47 | 49 |
| Alimentary System | | | |
| Gallbladder | (31) | (29) | (35) |
| Dilatation | | | 1 (3%) |
| Epithelium, hyperplasia, papillary | | | 1 (3%) |
| Intestine large, cecum | (34) | (35) | (37) |
| Hyperplasia, lymphoid | | 1 (3%) | 3 (8%) |
| Intestine large, colon | (36) | (38) | (39) |
| Hyperplasia, lymphoid | 1 (3%) | | |
| Intestine large, rectum | (32) | (32) | (31) |
| Serosa, inflammation, suppurative | | 1 (3%) | |
| Intestine small, duodenum | (32) | (30) | (34) |
| Hyperplasia, lymphoid | | | 1 (3%) |
| Mucosa, atrophy | 3 (9%) | 7 (23%) | 3 (9%) |
| Intestine small, ileum | (33) | (32) | (35) |
| Hyperplasia, lymphoid | 5 (15%) | 3 (9%) | 5 (14%) |
| Mucosa, atrophy | 3 (9%) | 5 (16%) | 4 (11%) |
| Peyer's patch, necrosis | 1 (3%) | | |
| Intestine small, jejunum | (32) | (31) | (36) |
| Hyperplasia, lymphoid | | | 1 (3%) |
| Mucosa, atrophy | 3 (9%) | 3 (10%) | 2 (6%) |
| Liver | (45) | (47) | (48) |
| Abscess | 1 (2%) | | 1 (2%) |
| Focal cellular change | 4 (9%) | 3 (6%) | 5 (10%) |
| Hematocyst | | 1 (2%) | |
| Hematopoietic cell proliferation | 2 (4%) | 2 (4%) | |
| Infarct | 2 (4%) | | |
| Inflammation, focal | | 3 (6%) | 1 (2%) |
| Mineralization, focal | | 1 (2%) | |
| Necrosis, focal | 4 (9%) | 5 (11%) | 4 (8%) |
| Pigmentation, hemosiderin, focal | | | 1 (2%) |
| Bile duct, hyperplasia, focal | | | 1 (2%) |
| Serosa, inflammation, suppurative | | | 1 (2%) |
| Pancreas | (42) | (39) | (42) |
| Serosa, inflammation, suppurative | | | 1 (2%) |
| Stomach, forestomach | (43) | (41) | (46) |
| Hyperplasia, squamous, focal | | 1 (2%) | 1 (2%) |
| Tooth | | (3) | |
| Dysplasia | | 3 (100%) | |
| Cardiovascular System | | | |
| Heart | (45) | (46) | (49) |
| Thrombosis | | 1 (2%) | 1 (2%) |
| Coronary artery, mineralization | | 1 (2%) | |
| Myocardium, degeneration, focal | 1 (2%) | | |
| Myocardium, fibrosis, focal | | 1 (2%) | |

NOT FOR DISTRIBUTION OR ATTRIBUTION

Board Draft

Lesions in Male Mice

C-29

TABLE C4
Summary of the Incidence of Nonneoplastic Lesions in Male Mice in the 2-Year Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|--|---------------------|---------------------|----------------------|
| Endocrine System | | | |
| Adrenal gland | (43) | (46) | (47) |
| Spindic cell, hyperplasia | 38 (88%) | 37 (80%) | 35 (74%) |
| Adrenal gland, cortex | (43) | (46) | (47) |
| Atrophy | 1 (2%) | | |
| Hyperplasia, focal | | 1 (2%) | |
| Vacuolization cytoplasmic, focal | | 3 (7%) | 4 (9%) |
| Parathyroid gland | (25) | (21) | (26) |
| Cyst | 3 (12%) | 1 (5%) | |
| Pituitary gland | (44) | (44) | (46) |
| Cyst | 1 (2%) | | 1 (2%) |
| Pigmentation, lipofuscin | 1 (2%) | | |
| Thyroid gland | (45) | (46) | (45) |
| Cyst | 2 (4%) | 1 (2%) | 1 (2%) |
| Follicular cell, hyperplasia | 4 (9%) | 8 (17%) | 8 (18%) |
| General Body System | | | |
| None | | | |
| Genital System | | | |
| Epididymis | (39) | (39) | (42) |
| Inflammation, suppurative | 1 (3%) | 1 (3%) | |
| Preputial gland | (8) | (6) | (8) |
| Dilatation | 7 (88%) | 6 (100%) | 8 (100%) |
| Inflammation | 3 (38%) | | 1 (13%) |
| Prostate | (40) | (43) | (44) |
| Inflammation, suppurative | 3 (8%) | 7 (16%) | 4 (9%) |
| Epithelium, hyperplasia | | 1 (2%) | |
| Seminal vesicle | (41) | (43) | (39) |
| Inflammation, suppurative | | 2 (5%) | 1 (3%) |
| Testes | (43) | (44) | (45) |
| Aspermatogenesis, diffuse | | | 1 (2%) |
| Atrophy, diffuse | | | 1 (2%) |
| Hypospermia | 1 (2%) | 2 (5%) | |
| Inflammation, suppurative | | 1 (2%) | |
| Seminiferous tubule, degeneration, focal | 3 (7%) | 4 (9%) | 1 (2%) |
| Hematopoietic System | | | |
| Bone marrow | (40) | (42) | (43) |
| Hyperplasia | 4 (10%) | 1 (2%) | 1 (2%) |
| Myelofibrosis | 2 (5%) | 2 (5%) | |
| Myeloid cell, hyperplasia | 4 (10%) | 7 (17%) | 1 (2%) |
| Lymph node | (45) | (46) | (48) |
| Iliac, hyperplasia, lymphoid | 1 (2%) | | |
| Iliac, hyperplasia, plasma cell | 1 (2%) | | |
| Lumbar, hyperplasia, lymphoid | 1 (2%) | 1 (2%) | |
| Lumbar, hyperplasia, plasma cell | | 1 (2%) | |
| Pancreatic, inflammation, granulomatous | | 1 (2%) | |
| Renal, depletion lymphoid | | | 1 (2%) |
| Renal, hyperplasia, lymphoid | | | 1 (2%) |

Board Draft

NOT FOR DISTRIBUTION OR ATTRIBUTION

C-30

Talc, NTP TR 421

TABLE C4
Summary of the Incidence of Nonneoplastic Lesions in Male Mice in the 2-Year Inhalation Study of Talc (continued)

| | 0 mg/m ³ | 6 mg/m ³ | 18 mg/m ³ |
|---|---------------------|---------------------|----------------------|
| Hematopoietic System (continued) | | | |
| Lymph node, bronchial | (32) | (39) | (44) |
| Abscess | | | 1 (2%) |
| Hyperplasia, histiocytic | 1 (3%) | 32 (82%) | 42 (95%) |
| Hyperplasia, histiocytic, lymphoid | | 1 (3%) | |
| Hyperplasia, lymphoid | 3 (9%) | 10 (26%) | 23 (52%) |
| Infiltration cellular, mixed cell | 3 (9%) | 1 (3%) | 3 (7%) |
| Inflammation, acute | 1 (3%) | | |
| Follicular, necrosis | 1 (3%) | | |
| Lymph node, mandibular | (23) | (23) | (19) |
| Hyperplasia, histiocytic | | 1 (4%) | |
| Hyperplasia, lymphoid | | | 1 (5%) |
| Follicular, necrosis | | | 1 (5%) |
| Lymph node, mediastinal | (9) | (10) | (7) |
| Hyperplasia, histiocytic | 1 (11%) | 1 (10%) | 2 (29%) |
| Hyperplasia, lymphoid | | 2 (20%) | |
| Lymph node, mesenteric | (36) | (39) | (40) |
| Depletion lymphoid | 1 (3%) | | 2 (5%) |
| Hyperplasia, lymphoid | 4 (11%) | 3 (8%) | 6 (15%) |
| Infiltration cellular, mixed cell | 18 (50%) | 20 (51%) | 13 (33%) |
| Inflammation, granulomatous | | 1 (3%) | |
| Thrombosis | | | 1 (3%) |
| Follicular, necrosis | | 6 (15%) | 2 (5%) |
| Spleen | (44) | (44) | (47) |
| Hematocyst | | 1 (2%) | |
| Hematopoietic cell proliferation | 6 (14%) | 7 (16%) | 10 (21%) |
| Hyperplasia, lymphoid | 3 (7%) | 2 (5%) | 3 (6%) |
| Hyperplasia, mast cell | | | 1 (2%) |
| Inflammation, granulomatous | | 1 (2%) | |
| Lymphoid follicle, depletion lymphoid | | 2 (5%) | 5 (11%) |
| Lymphoid follicle, necrosis | 2 (5%) | 5 (11%) | 1 (2%) |
| Thymus | (34) | (33) | (40) |
| Cyst | 3 (9%) | 2 (6%) | 1 (3%) |
| Hyperplasia, lymphoid | | | 1 (3%) |
| Inflammation, granulomatous | | 1 (3%) | |
| Necrosis | 1 (3%) | | 2 (5%) |
| Cortex, depletion lymphoid | 6 (18%) | 10 (30%) | 8 (20%) |
| Epithelial cell, hyperplasia, focal | 1 (3%) | | |
| Integumentary System | | | |
| Skin | (44) | (45) | (48) |
| Abscess | | 1 (2%) | |
| Alopecia | 1 (2%) | | 1 (2%) |
| Inflammation, acute | | 2 (4%) | |
| Ulcer, focal | | 2 (4%) | |
| Musculoskeletal System | | | |
| Bone | (46) | (47) | (49) |
| Rib, cartilage, fracture healed | 1 (2%) | | |
| Nervous System | | | |
| Brain | (46) | (47) | (48) |
| Mineralization, focal | 37 (80%) | 39 (83%) | 38 (79%) |

NOT FOR DISTRIBUTION OR ATTRIBUTION

Board Draft