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FYI-0101-1399

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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January 02, 2001

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Dear Document Control Office:

In compliance with the National Toxicology Program's (NTP) mission to keep our colleagues informed of the current NTP findings during ongoing studies, a copy of the revised Summary Pathology Tables for the chronic Dosed Feed study on O-NITROTOLUENE (88-72-2) are enclosed for your review.

The NTP assembles a Pathology Working Group to review every study and to resolve any differences between the study laboratory and quality assessment pathology evaluations. Please note that the PWG conclusion of the study results is based solely on the pathology for this study and may not reflect final NTP conclusions. In determining final conclusions, the NTP assesses a broad array of information that includes other results from this study and historical control data.

The Summary Pathology Tables contain the Incidence Rates of Neoplastic and Non-neoplastic Lesion data and the Statistical Analysis of Primary Tumors data pertaining to the laboratory animals. All study data are subject to an NTP retrospective audit and the interpretation may be modified based on the findings.

A wide variety of NTP information is also available in electronic format on the world-wide web, for example, the NTP Annual Plan, abstracts of NTP Reports, study data, and the status of all NTP studies. To view this information requires access to the internet and a Web browser such as Netscape Navigator or Internet Explorer. To access the NTP home page, use the URL http://ntp-server.niehs.nih.gov/. Comments on the usefulness of this site and suggestions for improvement are encouraged.

Please contact Central Data Management (CDM) at (919)541-3419 if you have any questions. You may also fax your requests for information to CDM at (919)541-3687 or send them via e-mail to cdm@niehs.nih.gov.

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Hard copies of documents such as NTP Technical Reports, short-term Toxicity Reports, and the Report on Carcinogens are available from the Environmental Health Information Service (EHIS). You can contact EHIS by phone at (919) 541-3841, by fax at (919)541-0273, or by e-mail at ehis@niehs.nih.gov.

Sincerely,

William Eastin

William Eastin, Ph.D.
Head, Information Systems & Central Files
Environmental Toxicology Program

Encls: Revised Pathology Summary Tables for Rats
cc: Central Data Management
Dr. J. Dunnick

# NATIONAL TOXICOLOGY PROGRAM

These reports were re-generated because the 2000/5000 ppm stop animals were left out. The revised reports are dated 12/13/00.

**TR-504 o-Nitrotoluene**

Pathology Tables - Rats

P03 - Incidence Rates of Non-Neoplastic Lesions

P05 - Incidence Rates of Neoplasms by Anatomic Site (systemic lesions abridged)

A 05

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
O-NITROTOLUENE



RATS/FINAL#1/REVISION#1

Facility: Southern Research Institute

Chemical CAS #: 88-72-2

Lock Date: 12/10/98

Cage Range: All

Reasons For Removal: 25022 Accidently Killed
25020 Natural Death
25019 Moribund Sacrifice
25021 Terminal Sacrifice

Removal Date Range: All

Treatment Groups:

| | |
|---|---|
| Include 002 | 0 PPM |
| Include 004 | 625 PPM |
| Include 006 | 1250 PPM |
| Include 008 | 2000 PPM |
| Include 001 | 0 PPM |
| Include 003 | 625 PPM |
| Include 005 | 1250 PPM |
| Include 007 | 2000 PPM |
| Include 009 | 2000 PPM(STOP) |
| Include 010 | 5000 PPM(STOP) |

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
O-NITROTOLUENE



| FISCHER 344 RATS FEMALE | 0 PPM | 625 PPM | 1250 PPM | 2000 PPM |
|---|---|---|---|---|
| DISPOSITION SUMMARY | | | | |
| Animals Initially In Study | 60 | 60 | 60 | 60 |
| Early Deaths | | | | |
| Moribund Sacrifice | 10 | 11 | 19 | 22 |
| Natural Death | 3 | 2 | 2 | 5 |
| Survivors | | | | |
| Terminal Sacrifice | 45 | 46 | 39 | 33 |
| Moribund Sacrifice | 1 | 1 | | |
| Natural Death | 1 | | | |
| Animals Examined Microscopically | 60 | 60 | 60 | 60 |
| ALIMENTARY SYSTEM | | | | |
| Intestine Large, Colon | (58) | (59) | (60) | (59) |
| Crypt, Diverticulum | 1 (2%) | | | |
| Intestine Large, Rectum | (60) | (60) | (60) | (58) |
| Fibrosis | | | 1 (2%) | |
| Intestine Large, Cecum | (58) | (59) | (60) | (59) |
| Edema | | 1 (2%) | 1 (2%) | |
| Liver | (60) | (59) | (60) | (60) |
| Angiectasis | 2 (3%) | 3 (5%) | 4 (7%) | 4 (7%) |
| Basophilic Focus | 51 (85%) | 56 (95%) | 60 (100%) | 54 (90%) |
| Clear Cell Focus | 16 (27%) | 30 (51%) | 28 (47%) | 33 (55%) |
| Degeneration, Cystic | | | 1 (2%) | 2 (3%) |
| Eosinophilic Focus | 5 (8%) | 12 (20%) | 25 (42%) | 32 (53%) |
| Hematopoietic Cell Proliferation | | 2 (3%) | 1 (2%) | 3 (5%) |
| Hemorrhage | | 1 (2%) | 1 (2%) | |
| Hepatodiaphragmatic Nodule | 9 (15%) | 13 (22%) | 10 (17%) | 7 (12%) |
| Infiltration Cellular, Mixed Cell | 15 (25%) | 11 (19%) | 6 (10%) | 12 (20%) |
| Mixed Cell Focus | 6 (10%) | 9 (15%) | 11 (18%) | 28 (47%) |
| Necrosis, Focal | | 1 (2%) | 3 (5%) | 5 (8%) |
| Regeneration, Diffuse | | | | 1 (2%) |
| Regeneration, Focal | 1 (2%) | 2 (3%) | | |
| Bile Duct, Hyperplasia | 7 (12%) | 2 (3%) | | |
| Centrilobular, Necrosis | 3 (5%) | | 2 (3%) | 2 (3%) |
| Hepatocyte, Vacuolization Cytoplasmic | 4 (7%) | 2 (3%) | 1 (2%) | |
| Kupffer Cell, Pigmentation | 3 (5%) | | | |
| Mesentery | (9) | (1) | (3) | (3) |
| Accessory Spleen | 2 (22%) | | 1 (33%) | 1 (33%) |
| Fat, Necrosis | 7 (78%) | 1 (100%) | 2 (67%) | |
| Pancreas | (60) | (59) | (60) | (60) |

a Number of animals examined microscopically at site and number of animals with lesion



A 07

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
O-NITROTOLUENE



| FISCHER 344 RATS FEMALE | 0 PPM | 625 PPM | 1250 PPM | 2000 PPM |
|---|---|---|---|---|
| ALIMENTARY SYSTEM - CONT | | | | |
| Atrophy | 13 (22%) | 10 (17%) | 7 (12%) | 4 (7%) |
| Acinus, Hyperplasia, Focal | 1 (2%) | 1 (2%) | 2 (3%) | 2 (3%) |
| Salivary Glands | (60) | (60) | (60) | (60) |
| Atrophy | 2 (3%) | 3 (5%) | 9 (15%) | 48 (80%) |
| Stomach, Forestomach | (59) | (59) | (60) | (60) |
| Erosion | 1 (2%) | | 1 (2%) | |
| Perforation | | 1 (2%) | | |
| Ulcer | 1 (2%) | 1 (2%) | | 1 (2%) |
| Epithelium, Hyperplasia | 5 (8%) | 3 (5%) | 1 (2%) | |
| Stomach, Glandular | (60) | (59) | (60) | (60) |
| Erosion | 1 (2%) | 1 (2%) | 1 (2%) | 3 (5%) |
| Ulcer | 2 (3%) | | 1 (2%) | 1 (2%) |
| Tooth | (2) | | | |
| Inflammation, Chronic | 1 (50%) | | | |
| Malformation | 2 (100%) | | | |
| CARDIOVASCULAR SYSTEM | | | | |
| Heart | (60) | (60) | (60) | (60) |
| Cardiomyopathy | 22 (37%) | 16 (27%) | 13 (22%) | 13 (22%) |
| Thrombosis | | | 1 (2%) | |
| Myocardium, Fibrosis | 1 (2%) | 1 (2%) | | 1 (2%) |
| ENDOCRINE SYSTEM | | | | |
| Adrenal Cortex | (60) | (60) | (60) | (59) |
| Accessory Adrenal Cortical Nodule | 8 (13%) | 10 (17%) | 8 (13%) | 10 (17%) |
| Degeneration, Fatty | 13 (22%) | 11 (18%) | 17 (28%) | 11 (19%) |
| Hyperplasia, Diffuse | 3 (5%) | 1 (2%) | | 1 (2%) |
| Hyperplasia, Focal | 9 (15%) | 6 (10%) | 14 (23%) | 15 (25%) |
| Hypertrophy, Focal | 6 (10%) | 7 (12%) | 6 (10%) | 7 (12%) |
| Necrosis | 1 (2%) | | | |
| Adrenal Medulla | (60) | (60) | (60) | (58) |
| Hyperplasia | 8 (13%) | 2 (3%) | 3 (5%) | 3 (5%) |
| Pituitary Gland | (59) | (60) | (60) | (60) |
| Pars Distalis, Angiectasis | 6 (10%) | 5 (8%) | 4 (7%) | 4 (7%) |
| Pars Distalis, Cyst | 22 (37%) | 20 (33%) | 22 (37%) | 24 (40%) |
| Pars Distalis, Hyperplasia, Focal | 12 (20%) | 6 (10%) | 12 (20%) | 9 (15%) |
| Pars Intermedia, Angiectasis | | 2 (3%) | 1 (2%) | |
| Pars Intermedia, Cyst | 3 (5%) | 1 (2%) | 1 (2%) | 1 (2%) |
| Thyroid Gland | (60) | (60) | (60) | (60) |

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
O-NITROTOLUENE



| FISCHER 344 RATS FEMALE | 0 PPM | 625 PPM | 1250 PPM | 2000 PPM |
|---|---|---|---|---|
| ENDOCRINE SYSTEM - CONT | | | | |
| Ultimobranchial Cyst | 1 (2%) | 1 (2%) | 1 (2%) | |
| C-Cell, Hyperplasia | 22 (37%) | 24 (40%) | 22 (37%) | 9 (15%) |
| Follicle, Cyst | | 2 (3%) | 1 (2%) | 1 (2%) |
| Follicular Cell, Hyperplasia | | 1 (2%) | | |
| GENERAL BODY SYSTEM | | | | |
| None | | | | |
| GENITAL SYSTEM | | | | |
| Clitoral Gland | (59) | (57) | (54) | (53) |
| Atrophy | 1 (2%) | 3 (5%) | 6 (11%) | 25 (47%) |
| Cyst | 2 (3%) | 4 (7%) | 4 (7%) | 2 (4%) |
| Hyperplasia | 5 (8%) | 1 (2%) | 4 (7%) | 1 (2%) |
| Inflammation, Chronic | 4 (7%) | 4 (7%) | 6 (11%) | 5 (9%) |
| Ovary | (60) | (59) | (60) | (60) |
| Angiectasis | | | | 2 (3%) |
| Cyst | 9 (15%) | 8 (14%) | 11 (18%) | 6 (10%) |
| Uterus | (60) | (59) | (60) | (60) |
| Angiectasis | 1 (2%) | | | |
| Cyst | | | | 1 (2%) |
| Hydrometra | 7 (12%) | 6 (10%) | 1 (2%) | 3 (5%) |
| Hyperplasia, Cystic | 8 (13%) | 6 (10%) | 9 (15%) | 8 (13%) |
| Inflammation, Chronic | 2 (3%) | 1 (2%) | 1 (2%) | |
| Epithelium, Hyperplasia | | | | 1 (2%) |
| HEMATOPOIETIC SYSTEM | | | | |
| Bone Marrow | (60) | (60) | (60) | (60) |
| Hyperplasia | 2 (3%) | 7 (12%) | 15 (25%) | 24 (40%) |
| Infiltration Cellular, Histiocyte | 2 (3%) | 1 (2%) | 1 (2%) | |
| Myelofibrosis | 1 (2%) | | | 2 (3%) |
| Lymph Node | (8) | (4) | (4) | (4) |
| Mediastinal, Hemorrhage | 1 (13%) | 1 (25%) | 1 (25%) | 3 (75%) |
| Mediastinal, Pigmentation | 6 (75%) | 1 (25%) | 1 (25%) | 3 (75%) |
| Renal, Hemorrhage | | | | 1 (25%) |
| Renal, Pigmentation | | | | 1 (25%) |
| Lymph Node, Mandibular | (60) | (60) | (59) | (59) |
| Ectasia | 1 (2%) | 3 (5%) | | 4 (7%) |

a Number of animals examined microscopically at site and number of animals with lesion

NTP Experiment-Test: 05203-08
Study Type: CHRONIC
Route: DOSED FEED

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
O-NITROTOLUENE

Report: PEIRPT03
Date: 12/13/00
Time: 08:31:25

| FISCHER 344 RATS FEMALE | 0 PPM | 625 PPM | 1250 PPM | 2000 PPM |
|---|---|---|---|---|
| HEMATOPOIETIC SYSTEM - CONT | | | | |
| Hemorrhage | 4 (7%) | 4 (7%) | 1 (2%) | 4 (7%) |
| Hyperplasia, Lymphoid | 3 (5%) | 5 (8%) | 6 (10%) | 15 (25%) |
| Pigmentation | 31 (52%) | 33 (55%) | 30 (51%) | 30 (51%) |
| Lymph Node, Mesenteric | (59) | (58) | (59) | (59) |
| Hemorrhage | 5 (8%) | 3 (5%) | 4 (7%) | 5 (8%) |
| Hyperplasia, Lymphoid | | | | 1 (2%) |
| Pigmentation | | 4 (7%) | 1 (2%) | 3 (5%) |
| Spleen | (60) | (59) | (60) | (59) |
| Congestion | | 1 (2%) | | |
| Fibrosis | 1 (2%) | | 1 (2%) | |
| Hematopoietic Cell Proliferation | 22 (37%) | 38 (64%) | 48 (80%) | 48 (81%) |
| Necrosis | 2 (3%) | | | |
| Pigmentation | 36 (60%) | 44 (75%) | 43 (72%) | 46 (78%) |
| Lymphoid Follicle, Atrophy | | 1 (2%) | | 1 (2%) |
| Thymus | (57) | (55) | (58) | (58) |
| Cyst | 1 (2%) | | 2 (3%) | 2 (3%) |
| INTEGUMENTARY SYSTEM | | | | |
| Mammary Gland | (60) | (60) | (59) | (60) |
| Dilatation | 40 (67%) | 30 (50%) | 29 (49%) | 24 (40%) |
| Galactocele | | 1 (2%) | | |
| Hyperplasia | 14 (23%) | 36 (60%) | 30 (51%) | 19 (32%) |
| Skin | (59) | (60) | (60) | (60) |
| Angiectasis | | | 1 (2%) | |
| Ulcer | 1 (2%) | | | |
| Subcutaneous Tissue, Edema | | | 1 (2%) | |
| MUSCULOSKELETAL SYSTEM | | | | |
| Bone | (60) | (60) | (60) | (60) |
| Cranium, Osteopetrosis | 2 (3%) | 6 (10%) | 6 (10%) | 10 (17%) |
| Femur, Osteopetrosis | 8 (13%) | 9 (15%) | 13 (22%) | 16 (27%) |
| NERVOUS SYSTEM | | | | |
| Brain | (60) | (60) | (60) | (60) |
| Compression | 6 (10%) | 10 (17%) | 5 (8%) | 3 (5%) |
| Hydrocephalus | 2 (3%) | 4 (7%) | | 3 (5%) |

a Number of animals examined microscopically at site and number of animals with lesion

NTP Experiment-Test: 05203-08
Study Type: CHRONIC
Route: DOSED FEED

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
O-NITROTOLUENE

Report: PEIRPT03
Date: 12/13/00
Time: 08:31:25

| FISCHER 344 RATS FEMALE | 0 PPM | 625 PPM | 1250 PPM | 2000 PPM |
|---|---|---|---|---|
| **RESPIRATORY SYSTEM** | | | | |
| Lung | (60) | (60) | (60) | (60) |
| Hemorrhage | 2 (3%) | 2 (3%) | 2 (3%) | 1 (2%) |
| Infiltration Cellular, Histiocyte | 52 (87%) | [illegible] (90%) | 53 (88%) | 55 (92%) |
| Alveolar Epithelium, Hyperplasia | 6 (10%) | [illegible] (23%) | 16 (27%) | 9 (15%) |
| Alveolar Epithelium, Hyperplasia, Atypical | | | | 1 (2%) |
| Nose | (60) | (60) | (60) | (60) |
| Foreign Body | 2 (3%) | | | 7 (12%) |
| Inflammation, Chronic | 2 (3%) | 1 [illegible] | 2 (3%) | 8 (13%) |
| Respiratory Epithelium, Hyperplasia | 2 (3%) | | | 3 (5%) |
| Respiratory Epithelium, Metaplasia, Squamous | | | 1 (2%) | 1 (2%) |
| **SPECIAL SENSES SYSTEM** | | | | |
| Eye | (3) | (3) | (2) | (1) |
| Cataract | 1 (33%) | 2 (67%) | 1 (50%) | 1 (100%) |
| Hemorrhage | 1 (33%) | | | |
| Inflammation, Chronic | 1 (33%) | 1 (33%) | | |
| Retina, Degeneration | 2 (67%) | 2 (67%) | 1 (50%) | 1 (100%) |
| **URINARY SYSTEM** | | | | |
| Kidney | (60) | (59) | (60) | (60) |
| Cyst | | 1 (2%) | 1 (2%) | |
| Hydronephrosis | | | 1 (2%) | |
| Infarct | 2 (3%) | | 1 (2%) | |
| Inflammation, Chronic | 2 (3%) | 1 (2%) | 1 (2%) | 1 (2%) |
| Nephropathy | 53 (88%) | 45 (76%) | 48 (80%) | 52 (87%) |
| Renal Tubule, Cytoplasmic Alteration | | 1 (2%) | 1 (2%) | |
| Renal Tubule, Degeneration, Hyaline | 9 (15%) | 10 (17%) | 4 (7%) | 11 (18%) |
| Renal Tubule, Necrosis | 2 (3%) | | | |
| Renal Tubule, Pigmentation | 9 (15%) | 10 (17%) | 7 (12%) | 17 (28%) |
| Transitional Epithelium, Hyperplasia | 1 (2%) | | 1 (2%) | 1 (2%) |
| Urinary Bladder | (60) | (59) | (60) | (60) |
| Transitional Epithelium, Hyperplasia | | | 1 (2%) | |

a Number of animals examined microscopically at site and number of animals with lesion

NTP Experiment-Test: 05203-08
Study Type: CHRONIC
Route: DOSED FEED

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
O-NITROTOLUENE

Report: PEIRPT03
Date: 12/13/00
Time: 08:31:25

| FISCHER 344 RATS MALE | 0 PPM | 625 PPM | 1250 PPM | 2000 PPM | 2000 PPM (STOP) | 5000 PPM (STOP) |
|---|---|---|---|---|---|---|
| DISPOSITION SUMMARY | | | | | | |
| Animals Initially In Study | 70 | 60 | 60 | 60 | 70 | 70 |
| Early Deaths | | | | | | |
| Moribund Sacrifice | 18 | 35 | 48 | 53 | 39 | 57 |
| Natural Death | 3 | 7 | 6 | 7 | 10 | 3 |
| Accidently Killed | | | 3 | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 38 | 18 | 3 | | 11 | |
| Natural Death | 1 | | | | | |
| Animals Examined Microscopically | 60 | 60 | 60 | 60 | 60 | 60 |
| ALIMENTARY SYSTEM | | | | | | |
| Intestine Large, Cecum | | | | | | |
| Edema | (60) | (60) | (60) | (58) | (59) | (60) |
| Liver | 1 (2%) | | | | 1 (2%) | |
| Angiectasis | (60) | (60) | (60) | (60) | (60) | (60) |
| Atrophy | | 1 (2%) | 2 (3%) | 2 (3%) | 3 (5%) | 2 (3%) |
| Basophilic Focus | 1 (2%) | 1 (2%) | 1 (2%) | 4 (7%) | | 3 (5%) |
| Clear Cell Focus | 38 (63%) | 22 (37%) | 21 (35%) | 25 (42%) | 31 (52%) | 17 (28%) |
| Cyst | 29 (48%) | 29 (48%) | 34 (57%) | 31 (52%) | 30 (50%) | 34 (57%) |
| Degeneration, Cystic | | | | 1 (2%) | | |
| Eosinophilic Focus | 3 (5%) | 3 (5%) | 1 (2%) | 2 (3%) | 6 (10%) | 3 (5%) |
| Fibrosis | 7 (12%) | 18 (30%) | 29 (48%) | 24 (40%) | 15 (25%) | 13 (22%) |
| Hematopoietic Cell Proliferation | | 1 (2%) | | | 2 (3%) | |
| Hemorrhage | | 6 (10%) | 2 (3%) | 2 (3%) | 11 (18%) | 6 (10%) |
| Hepatodiaphragmatic Nodule | 2 (3%) | | 2 (3%) | 2 (3%) | 2 (3%) | |
| Infiltration Cellular, Mixed Cell | 5 (8%) | 8 (13%) | 8 (13%) | 5 (8%) | 10 (17%) | 4 (7%) |
| Mixed Cell Focus | 1 (2%) | 5 (8%) | 11 (18%) | 20 (33%) | 15 (25%) | 33 (55%) |
| Necrosis, Focal | 5 (8%) | 7 (12%) | 12 (20%) | 6 (10%) | 12 (20%) | 8 (13%) |
| Bile Duct, Hyperplasia | 3 (5%) | 4 (7%) | 6 (10%) | 6 (10%) | 2 (3%) | 3 (5%) |
| Centrilobular, Necrosis | 53 (88%) | 37 (62%) | 7 (12%) | | 6 (10%) | 1 (2%) |
| Hepatocyte, Vacuolization Cytoplasmic | 1 (2%) | 3 (5%) | 8 (13%) | 5 (8%) | 9 (15%) | 3 (5%) |
| Kupffer Cell, Pigmentation | 4 (7%) | 2 (3%) | 1 (2%) | 1 (2%) | 1 (2%) | 6 (10%) |
| Mesentery | 4 (7%) | | 1 (2%) | 3 (5%) | | 2 (3%) |
| Accessory Spleen | (16) | (6) | (5) | (4) | (1) | (3) |
| Congestion | 3 (19%) | | | 3 (75%) | | |
| Hemorrhage | 3 (19%) | | | | | |
| Fat, Necrosis | | 1 (17%) | | | | |
| Oral Mucosa | 13 (81%) | 3 (50%) | 5 (100%) | 1 (25%) | 1 (100%) | |
| Hyperplasia | | | (1) | (1) | | |
| | | | 1 (100%) | | | |

a Number of animals examined microscopically at site and number of animals with lesion

NTP Experiment-Test: 05203-08
Study Type: CHRONIC
Route: DOSED FEED

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
O-NITROTOLUENE

Report: PETRPT03
Date: 12/13/00
Time: 08:31:25

| FISCHER 344 RATS MALE | 0 PPM | 625 PPM | 1250 PPM | 2000 PPM | 2000 PPM (STOP) | 5000 PPM (STOP) |
|---|---|---|---|---|---|---|
| ALIMENTARY SYSTEM - CONT | | | | | | |
| Pancreas | (60) | (60) | (60) | (60) | (60) | (60) |
| Atrophy | 11 (18%) | 14 (23%) | 7 (12%) | 4 (7%) | 11 (18%) | 9 (15%) |
| Acinus, Hyperplasia, Focal | 1 (2%) | 2 (3%) | 3 (5%) | 4 (7%) | 6 (10%) | 3 (5%) |
| Salivary Glands | (60) | (60) | (59) | (60) | (58) | (59) |
| Atrophy | | 2 (3%) | 18 (31%) | 43 (72%) | 16 (28%) | 49 (83%) |
| Stomach, Forestomach | (59) | (60) | (60) | (60) | (60) | (60) |
| Edema | 4 (7%) | 2 (3%) | | 1 (2%) | 2 (3%) | |
| Ulcer | 2 (3%) | 2 (3%) | 1 (2%) | 1 (2%) | 1 (2%) | |
| Epithelium, Hyperplasia | 6 (10%) | 2 (3%) | 1 (2%) | 2 (3%) | 4 (7%) | 1 (2%) |
| Stomach, Glandular | (59) | (60) | (60) | (60) | (60) | (60) |
| Edema | | | | 1 (2%) | 1 (2%) | |
| Erosion | 4 (7%) | 2 (3%) | 7 (12%) | 7 (12%) | 7 (12%) | 3 (5%) |
| Infiltration Cellular, Lymphoid | 1 (2%) | | | | | |
| Perforation | | | | | 1 (2%) | |
| Ulcer | 1 (2%) | 2 (3%) | | 3 (5%) | 1 (2%) | 1 (2%) |
| Tongue | (1) | | (1) | | | |
| Epithelium, Hyperplasia | 1 (100%) | | | | | |
| Tooth | | | | (1) | | (1) |
| Malformation | | | | 1 (100%) | | |
| CARDIOVASCULAR SYSTEM | | | | | | |
| Heart | (60) | (60) | (60) | (60) | (60) | (60) |
| Cardiomyopathy | 40 (67%) | 43 (72%) | 43 (72%) | 37 (62%) | 39 (65%) | 46 (77%) |
| Thrombosis | 1 (2%) | 1 (2%) | 1 (2%) | | 4 (7%) | 1 (2%) |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (60) | (60) | (60) | (60) | (60) | (60) |
| Accessory Adrenal Cortical Nodule | 13 (22%) | 12 (20%) | 13 (22%) | 10 (17%) | 14 (23%) | 9 (15%) |
| Degeneration, Fatty | 16 (27%) | 10 (17%) | 11 (18%) | 4 (7%) | 14 (23%) | 12 (20%) |
| Hyperplasia, Diffuse | | | 1 (2%) | 3 (5%) | | 2 (3%) |
| Hyperplasia, Focal | 6 (10%) | 2 (3%) | 6 (10%) | 3 (5%) | 4 (7%) | 6 (10%) |
| Hypertrophy, Focal | 3 (5%) | 2 (3%) | 2 (3%) | | 3 (5%) | 2 (3%) |
| Necrosis | | | | | | 1 (2%) |
| Adrenal Medulla | (60) | (60) | (60) | (59) | (60) | (60) |
| Hyperplasia | 7 (12%) | 4 (7%) | 2 (3%) | | 3 (5%) | 1 (2%) |
| Islets, Pancreatic | (60) | (60) | (60) | (60) | (60) | (60) |
| Hyperplasia | 2 (3%) | | | 2 (3%) | 2 (3%) | 10 (17%) |
| Pigmentation | 1 (2%) | | | 2 (3%) | | 11 (18%) |
| Parathyroid Gland | (58) | (55) | (59) | (58) | (58) | (57) |

a Number of animals examined microscopically at site and number of animals with lesion



A 13

NTP Experiment-Test: 05203-08
Study Type: CHRONIC
Route: DOSED FEED

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
O-NITROTOLUENE

Report: PEIRPT03
Date: 12/13/00
Time: 08:31:25

| FISCHER 344 RATS MALE | 0 PPM | 625 PPM | 1250 PPM | 2000 PPM | 2000 PPM (STOP) | 5000 PPM (STOP) |
|---|---|---|---|---|---|---|
| ENDOCRINE SYSTEM - CONT | | | | | | |
| Hyperplasia | | | | | | |
| Pituitary Gland | | 1 (2%) | | | | |
| Pars Distalis, Angiectasis | (59) | (60) | (58) | (59) | (57) | (59) |
| Pars Distalis, Cyst | 3 (5%) | | 7 (12%) | 2 (3%) | 4 (7%) | 4 (7%) |
| Pars Distalis, Cytoplasmic Alteration | 2 (3%) | 6 (10%) | 3 (5%) | 4 (7%) | 3 (5%) | 6 (10%) |
| Pars Distalis, Hyperplasia, Focal | 1 (2%) | | 1 (2%) | 4 (7%) | 1 (2%) | 42 (71%) |
| Pars Intermedia, Cyst | 10 (17%) | 13 (22%) | 13 (22%) | 10 (17%) | 9 (16%) | 15 (25%) |
| Thyroid Gland | | 1 (2%) | 1 (2%) | | 1 (2%) | 2 (3%) |
| Ultimobranchial Cyst | (59) | (60) | (60) | (60) | (60) | (60) |
| C-Cell, Hyperplasia | | 1 (2%) | 2 (3%) | 3 (5%) | 4 (7%) | 3 (5%) |
| Follicle, Cyst | 10 (17%) | 11 (18%) | 9 (15%) | 7 (12%) | 9 (15%) | 6 (10%) |
| Follicular Cell, Hyperplasia | 3 (5%) | 2 (3%) | | | | |
| | 1 (2%) | | | | | |
| GENERAL BODY SYSTEM | | | | | | |
| Peritoneum | (3) | (21) | (33) | (46) | (47) | (54) |
| Mesothelium, Hyperplasia | 1 (33%) | 1 (5%) | 4 (12%) | 2 (4%) | 3 (6%) | |
| GENITAL SYSTEM | | | | | | |
| Epididymis | (60) | (60) | (59) | (60) | (60) | (58) |
| Atypia Cellular | 39 (65%) | 32 (53%) | 27 (46%) | 21 (35%) | 24 (40%) | 28 (48%) |
| Fibrosis | | 2 (3%) | | | | |
| Inflammation, Chronic | | 1 (2%) | | | 2 (3%) | |
| Preputial Gland | (60) | (59) | (58) | (56) | (60) | (59) |
| Atrophy | 7 (12%) | 9 (15%) | 35 (60%) | 41 (73%) | 38 (63%) | 54 (92%) |
| Cyst | 1 (2%) | 4 (7%) | 1 (2%) | | 1 (2%) | 1 (2%) |
| Hyperplasia | | 1 (2%) | | | | |
| Inflammation, Chronic | 40 (67%) | 43 (73%) | 36 (62%) | 27 (48%) | 33 (55%) | 14 (24%) |
| Prostate | (60) | (59) | (60) | (60) | (60) | (60) |
| Inflammation, Chronic | 24 (40%) | 14 (24%) | 18 (30%) | 9 (15%) | 17 (28%) | 8 (13%) |
| Epithelium, Hyperplasia | | | | | 1 (2%) | |
| Ventral, Hyperplasia | 18 (30%) | 3 (5%) | 9 (15%) | 1 (2%) | 4 (7%) | 1 (2%) |
| Testes | (60) | (60) | (60) | (60) | (60) | (60) |
| Angiectasis | | | | 2 (3%) | | 1 (2%) |
| Hemorrhage | | | | | 2 (3%) | |
| Germinal Epithelium, Atrophy | 13 (22%) | 21 (35%) | 12 (20%) | 19 (32%) | 18 (30%) | 53 (88%) |
| Interstitial Cell, Hyperplasia | 10 (17%) | 14 (23%) | 13 (22%) | 31 (52%) | 15 (25%) | 4 (7%) |

a Number of animals examined microscopically at site and number of animals with lesion