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January 16, 2002

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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 Pathology Working Group (PWG) report and the Summary Pathology Tables for the chronic Inhalation study on PROPYLENE GLYCOL MONO-T-BUTYL ETHER (57018-52-7) 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: PWG Report and Pathology Summary Tables for Rats & Mice
cc: Central Data Management

NATIONAL TOXICOLOGY PROGRAM

TR-515 Propylene Glycol Mono-T-Burtyl Ether

Pathology Tables - Rats

P03 - Incidence Rates of Non-Neoplastic Lesions - 2 year study

P05 - Incidence Rates of Neoplasms by Anatomic Site (systemic lesions abridged) - 2 year study

P08 - Statistical Analysis of Primary Tumors

Pathology Tables - Mice

P03 - Incidence Rates of Non-Neoplastic Lesions - 2 year study

P05 - Incidence Rates of Neoplasms by Anatomic Site (systemic lesions abridged) - 2 year study

P08 - Statistical Analysis of Primary Tumors

P18 – Incidence Rates of Nonneoplastic Lesions by Anatomic Site (a) with Average Severity Grades (b)

PATHOLOGY WORKING GROUP
CHAIRPERSON'S REPORT

TWO YEAR CHRONIC STUDY OF PROPYLENE GLYCOL MONO-t-BUTYL ETHER (PGMBE) (C90004/90004-07) ADMINISTERED BY INHALATION IN F344 RATS

DATE OF PWG: August 2, 2001

LOCATION OF PWG: NIEHS, Research Triangle Park, NC

PARTICIPANTS: Drs. R. Herbert (NIEHS), R. Maronpot (NIEHS), G. Parker (ILS-PWG Chairperson), G. Pearse (NIEHS), R. Renne (Battelle), C. Shackleford (EPL), R. Sills (NIEHS), A. Suttie (ILS), G. Willson (EPL), and P. Blackshear (ILS-observer).

SUMMARY OF FINDINGS FROM PWG

The PWG was convened to evaluate selected H & E slides from a two-year chronic study of propylene glycol mono-t-butyl ether (PGMBE) administered by whole-body inhalation exposure to Fischer 344 rats.

The following is a summary of findings related to exposure to PGMBE:

- Dose-related increase in the incidence of renal tubular epithelial hyperplasia and hyaline droplet formation in tubular epithelial cells in males at 300 and 1200 ppm.
- Dose-related increase in the incidence of renal papilla mineralization in males at 75, 300, and 1200 ppm
- Increased mean severity of nephropathy in males at 75, 300 and 1200 ppm.
- Increased incidence of renal tubular neoplasms in males at 300 and 1200 ppm.
- Increased incidence of transitional epithelial hyperplasia in the renal pelvis of males at 300 and 1200 ppm.
- Increased incidence of hepatocellular clear cell foci in females at 1200 ppm.
- Increased incidence of hepatocellular basophilic foci in males at 1200 ppm and females at 75, 300, or 1200 ppm.
- Increased incidence of hyaline degeneration of olfactory epithelium in males and females at all dosage levels.
- Increased incidence of glandular dilatation in nasal cavity of males at 300 and 1200 ppm

- Increased incidence of goblet cell hyperplasia in nasal cavity of males at 1200 ppm.
- Increased incidence of corneal mineralization in females at 1200 ppm.
- Slight increase in the incidence of transitional epithelial neoplasms in the urinary bladder of males and females at 1200 ppm.

INTRODUCTION

Propylene glycol mono-t-butyl ether is a solvent used in a variety of commercial applications, including cleaners, inks, lacquers, adhesives and as a coalescent in latex paints. PGMBE has been formulated as a potential substitute for ethylene glycol ethers, which are teratogenic and cause bone marrow depression and/or hemolysis. PGMBE did not cause delayed contact sensitivity in guinea pigs, was only moderately toxic to rats, and did not cause developmental toxicity in rabbits or rats in previous studies. Exact annual production figures are not available, but production was estimated to be less than 1 million pounds in 1995. Occupational exposure occurs by inhalation or dermal contract during solvent manufacturing or use. PGMBE was nominated for study by the US Consumer Product Safety Commission based on its widespread use, potential for exposure at high concentrations, and limited toxicological information.

In the NTP two-week repeated dose inhalation study, five Fisher 344/N (F344) rats/sex/group and five male NCI Black Reiter (NBR) were exposed to target concentrations of 0, 75, 150, 300, 600, or 1200 ppm for 12 days. There were no effects on survival, clinical signs or body weight gains. Exposure concentrations in the NTP 13-week subchronic study were the same as the two-week study, but only F344 rats were employed. The most significant histologic alteration noted in the prechronic studies was hyaline droplet accumulation in renal cortical tubular epithelial cells in male F344 rats. The maximum tolerated dose was not exceeded in the prechronic studies. A toxicokinetic study indicated elimination of PGMBE from the blood was saturated at an exposure concentration of 1200 ppm.

STUDY DESIGN

Male and female F344 rats were exposed via whole body inhalation to PGMBE at target concentrations of 0, 75, 300, or 1200 ppm. The study was conducted at Battelle Northwest, Richland, WA. The Study Pathologist (SP) was Dr. R. Renne. The Quality Assessment Pathologist (QAP) was Dr. G. Willson of EPL.

STUDY RESULTS

Survival

Survival of males in the 300 ppm group was significantly reduced as compared to controls. Survival of remaining male groups and all treated female groups was similar to that of controls.

Clinical Observations

There were no clinical observations believed to be caused by exposure to PGMBE.

Body weights

Group mean body weights of males and females from the 1200 ppm group were decreased compared to controls, starting at Week 40 for males and Week 60 for females. At study termination the group mean body weight of 1200 ppm females was significantly (8.2%) less than controls. At study termination the body weight of 1200 ppm males was insignificantly (5.3%) less than controls. Group mean body weights of males and females from the 75 and 300 ppm were similar to those of the controls though out the study, though a slight reduction was noted in males and females from the 300 ppm group during the last three months of the study.

Necropsy

There was an increased incidence of opacity or pale foci in the eyes of females from the 1200 ppm group. There were two grossly visible renal masses that histologic examination proved to be tubular neoplasms, one mass that proved to be a tubular carcinoma and another mass that proved to be a stromal nephroma.

Histopathology

The study pathologist identified the following potential treatment-related histologic alterations:

Kidney- increased incidence of renal tubular neoplasms in males

Kidney- increased severity of spontaneous nephropathy in males.

Kidney- tubular epithelial hyperplasia in males.

Kidney- mineralization of renal papilla in males.

Kidney- hyaline droplet accumulation in renal cortical tubules in males

Kidney- hyperplasia of the transitional epithelium of the renal pelvis in males

Urinary bladder- transitional cell carcinoma in one male and one female from the 1200 ppm group

Liver- clear cell foci in females

Nose- hyaline droplet degeneration in olfactory epithelium

The initial histopathologic evaluation revealed no histologic correlate of the eye opacities noted at necropsy.

QUALITY ASSURANCE REVIEW

The quality assurance review generally confirmed the findings of the study pathologist. In addition, the quality assurance pathologist identified the following as potential treatment-related lesions:

Liver- basophilic foci in males and females

Eye- corneal mineralization in females

The quality assurance pathologist diagnosed six hepatocellular adenomas in males from the 1200 ppm group, as opposed to the five hepatocellular adenomas that were diagnosed by the study pathologist. The incidence of hepatocellular adenomas in males from the control, 300 and 1200 ppm groups was above the historical control level (3/50, 0/50, 2/49 and 6/50 in 0, 75, 300 and 1200 ppm groups, respectively). The incidence of basophilic foci combined with hepatocellular adenoma incidence aroused suspicion of a treatment-related effect on hepatocellular proliferative lesions.

CONDUCT OF THE PWG

In preparation for the PWG, the PWG Chairperson reviewed the study pathology tables (summary and individual animal data), the study Final Report, the Quality Assessment Report, relevant literature and H&E-stained slides selected for the QA review. The Chairperson then selected slides for review by the PWG. The selected slides included the following:

1. all renal tumors
2. examples of renal tubular hyperplasia
3. all renal tubular proliferations in which there was a disagreement between SP and QAP
4. examples of renal papillary mineralization
5. examples of renal tubular hyaline droplet accumulation
6. examples of transitional epithelial hyperplasia of the renal pelvis
7. examples of renal tubular pigmentation
8. all urinary bladder tumors
9. all hepatic basophilic foci recorded by QAP
10. examples of hepatic clear cell foci
11. examples of hepatic lesions in which there was disagreement in diagnosis of clear cell foci
12. examples of hyaline droplet degeneration in the nasal epithelium
13. all corneal mineralization lesions as recorded by QAP
14. miscellaneous lesions as selected by the Chairperson

PWG participants reviewed all the selected slides, with the following exceptions:

1. The PWG reviewed only 15 of the cases of hepatic basophilic foci. After voting on these 15 cases the PWG determined there was excellent agreement between QAP and PWG, and elected to forego review and accept QAP's diagnosis of the remaining examples of hepatic basophilic foci.

2. The PWG reviewed examples of renal tubular hyperplasia and, after determining the consensus diagnosis, elected to forego review and accept QAP's diagnosis of the remaining cases of renal tubular hyperplasia.

PWG RESULTS

Kidney

The PWG agreed with the diagnosis of renal tubular adenoma and carcinoma and, to a great extent, the diagnosis of renal tubular hyperplasia. The PWG concurred with the diagnosis and grading of hyaline droplet degeneration, papillary mineralization and hyperplasia of the transitional epithelium of the renal pelvis. The PWG concluded the renal tubular pigmentation was not a significant issue in the study and that there was no benefit to be derived from an exhaustive post-PWG effort to differentiate between tubular pigmentation and hyaline droplet degeneration.

Urinary Bladder

The consensus opinion of the PWG was that the urinary bladder lesion in 1200 ppm female #711 was a papilloma rather than a transitional cell carcinoma, as originally recorded. The unusual histomorphology of the lesion was discussed, and it was questioned whether the lesion truly originated in the urinary bladder. Gross necropsy records were reviewed during the PWG and it was found that female #711 had a grossly visible mass in the urinary bladder.

Liver

The PWG agreed with QAP's interpretation of an increased incidence of basophilic foci in the liver of all treated male groups. Attendees discussed the potential significance of this finding, particularly in view of the equivocal increase in incidence of hepatocellular neoplasms in the 1200 ppm males. It was noted that the control males also had a high incidence of basophilic foci and that the study revealed no evidence of progression from focus to adenoma to carcinoma. There was discussion as to whether basophilic foci were associated with mononuclear leukemia. Dr. Maronpot presented published data indicating there is increased incidence and altered morphology of some types of hepatocellular foci in leukemic rats, but the incidence of basophilic foci is reduced in F344 rats with mononuclear cell leukemia [Harada, 1990 #2500][Maronpot, 1989 #2501].

Nose

The PWG agreed with the diagnosis and grading of hyaline droplet accumulation in the olfactory epithelium. Comments were made regarding the common occurrence of this nonspecific finding in chemically-treated rats, as well as the lack of any apparent progression to an overtly pathologic tissue alteration despite prolonged chemical exposure.

Eye

The PWG agreed with QAP's diagnoses of corneal mineralization in ten females from the 1200 ppm group. It was noted there was poor correlation between the corneal mineralization and the eye opacities that were noted at necropsy.

MISCELLANEOUS ISSUES

There was discussion as to the customary procedure for recording mesotheliomas that involved multiple sites. SP had recorded those lesions under the affected organs, while QAP had grouped the lesions under a single site of "peritoneum". The PWG agreed the lesions should be recorded under the individual affected organs. The TDMS system will group the lesions for purposes of analysis.

There was discussion as to the proper criteria for recording the diagnosis of testicular germinal epithelial atrophy, particularly when the atrophy occurs in conjunction with testicular neoplasms such as interstitial cell adenomas. The PWG concluded that atrophy should be recorded only when it does not appear to be due to the presence of a testicular neoplasm. The PWG chairperson was instructed to review all examples of testicular atrophy and make a subjective determination of whether the atrophy was related to the presence of a tumor. Only those cases of atrophy that are not tumor-associated should be recorded.

POST-PWG ACTION ITEMS

The sections of testis have been reviewed to determine the relationship between interstitial cell adenoma and atrophy of germinal epithelium. The diagnosis of atrophy was deleted in animals in which the atrophy appeared to be tumor-related. Hand tabulation of the remaining cases of testicular atrophy suggests there was no treatment-related alteration in the incidence of testicular atrophy.

Step-sections of kidneys are being prepared in an effort to locate all proliferative lesions. These sections will be examined by another pathologist and findings addressed in a separate report.

SUMMARY

Male F344 rats subjected to whole-body inhalation exposure to PGMBE had a spectrum of renal lesions that included hyperplasia of cortical tubular epithelium, hyaline droplet accumulation in cortical tubular epithelial cells, increased severity of spontaneous neophropathy, mineralization of the renal papilla, hyperplasia of the transitional epithelium of the renal pelvis, and a small number of renal tubular neoplasms. There was an increased incidence of hepatocellular clear cell foci in females exposed at 1200 ppm and an increased incidence of hepatocellular basophilic foci in males at 1200 ppm and females at 75, 300, and 1200 ppm. Treatment-related changes in the nasal cavity included an increase in the incidence of hyaline droplet accumulation in olfactory epithelial cells, increased incidence of glandular dilatation in males exposed at 300 or 1200 ppm, and increased incidence of goblet cell hyperplasia in males exposed at 1200 ppm. Females exposed at 1200 ppm had a moderate incidence of corneal mineralization, which correlated poorly with gross necropsy observations of ocular opacities.

George A. Parker, D.V.M., Ph.D., DACVP, DABT
PWG Chairperson

12 Sep 01
Date

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PATHOLOGY WORKING GROUP
CHAIRPERSON'S REPORT

TWO YEAR CHRONIC INHALATION STUDY OF PROPYLENE GLYCOL MONO-t-BUTYL ETHER (PGMBE) (C90004/90004-06) IN B6C3F1 MICE

DATE OF PWG: July 31, 2001

LOCATION OF REVIEW: NIEHS, Research Triangle Park, NC

PARTICIPANTS:

Drs. Ronald Herbert (NIEHS – NTP Study Pathologist), James Hailey (NIEHS), Robert Sills (NIEHS), Robert Maronpot (NIEHS), Gail Pearse (NIEHS), John Cullen (N.C. State University), Gabrielle Wilson (EPL), Cynthia Shackelford (EPL – QA Pathologist), Andrew Suttie (ILS), Catherine Picut (ILS-PWG Chairperson), and Pamela Blackshear (ILS – observer).

SUMMARY OF FINDINGS FROM THE PWG

The PWG was convened to evaluate selected H&E slides from this two-year chronic inhalation study in B6C3F1 mice exposed to Propylene Glycol Mono-t-Butyl Ether (PGMBE). The target organs are the liver in both sexes and the eye in females. The following is a summary of definitive treatment-related lesions.

- LIVER: Chronic exposure of mice to PGMBE caused increased incidences hepatocellular adenomas, hepatocellular carcinomas, hepatoblastomas, and eosinophilic foci in the liver of both sexes. There also was an increased incidence and severity of multinucleated hepatocytes in the high dose male mice.

- EYE: Treatment with PGMBE resulted in an increased incidence of corneal mineralization in the high dose female mice.

INTRODUCTION

Propylene Glycol Mono-t-Butyl Ether (PGMBE) is a solvent used in cleaners, inks, lacquers, adhesives, and latex paints. There is high potential for human inhalation or dermal exposure during the manufacturing or use of the solvent.

In a 14-day pre-chronic repeated dose study of PGMBE in rats using target concentrations of 0, 75, 150, 300, 600 and 1200 ppm, there were no notable pathologic effects (Chou, et al, 1996). In the 13 week sub-chronic study in rats using the same target concentrations as in the 14 day study, the only pathologic effects were squamous metaplasia of the nasal mucosa and centrilobular cytomegaly in the liver in the high dose animals only (Chou, et al, 1997).

STUDY DESIGN

In this inhalation study, PGMBE was administered to mice at a dose level of 0 ppm, 75 ppm, 300 ppm, or 1200 ppm for two years.

The doses and numbers of animals examined microscopically per group are summarized below:

Dose Group	Female	Male
0 ppm	50	50
75 ppm	50	50
300 ppm	50	50
1200 ppm	50	50

The study was conducted at Batelle Northwest, Richland, Washington. The Study Pathologist (SP) was Dr. Sondra Grumbein. The Quality Assessment Pathologist (QAP) was Dr. Cynthia Shackelford of EPL.

STUDY RESULTS

Morbidity, Mortality, Clinical Signs, Organ Weights, Body Weight

Treatment of mice with PGMBE had no effect on morbidity, mortality, body weights or organ weights. The following table depicts the numbers of animals in each dose group surviving to terminal sacrifice:

Dose	0 ppm	75 ppm	300 ppm	1200 ppm
Males	35	40	40	35
Females	39	36	41	38

The only treatment-related clinical signs reported were ataxia and shallow breathing in the high dose groups, and these clinical signs were only observed during the first 6 months of exposure. In the high dose female mice, 28 out of 50 mice had pale foci noted on the cornea.

CONDUCT OF THE PWG

The PWG convened to review selected slides from B6C3F1 mice exposed to whole body inhalation of PGMBE for two years.

Before the PWG, the chairperson reviewed the laboratory reports and the SP's pathology narratives, the summary and individual animal pathology tables, the quality assessment reports, and microslides from the studies. The PWG chairperson selected a set of slides for review by the PWG which included examples of treatment related lesions as well as slides for which there were differences of opinion in diagnosis among the SP, QAP or PWG chair. The PWG consensus opinion for each slide examined, including any additional diagnoses made by the PWG, was recorded on the PWG chairperson's worksheets attached to this report.

Histopathology

Liver

There was good correlation between the SP and the QAP concerning the lesions in the liver of male and female mice. The PWG reviewed examples of eosinophilic foci, hepatocellular adenomas, hepatocellular carcinomas and hepatoblastomas in the treated animals, and confirmed that exposure to PGMBE caused a dose- related increase in the incidence of these lesions in both sexes. The criteria used for diagnosing these various lesions were those described in Maronpot, 1999 (pp140 – 151).

The QAP report stated several of the hepatocellular adenomas in the treated mice were morphologically different from the adenomas occurring in the control animals. The adenomas in the treated animals generally were comprised of large eosinophilic cells with considerable loss of architecture, and were further characterized by occasional rosettes of small basophilic cells and pseudogland formation. The PWG reviewed many of these treatment related adenomas and confirmed their diagnosis as adenomas. The PWG further noted that many of the adenomas in the treated animals had cellular atypism, cytoplasmic inclusions and oval cell proliferation.

The PWG reviewed an additional 15 cases involving discrepancies between the SP, QAP and PWG chair regarding diagnoses of proliferative lesions in the liver. Each of these discrepancies was resolved by consensus opinion.

The PWG also reviewed several examples of the lesion diagnosed as "syncitial alteration" in the liver of high dose male mice. The PWG confirmed that there is an increase in incidence and severity of multinucleated hepatocytes in the high dose male mice. The PWG was of the unanimous opinion that the term "multinucleated hepatocytes" was more appropriate terminology than "syncitial alteration", since the latter term implies a certain pathogenesis.

The criteria used for diagnosing and grading the severity of multinucleated hepatocytes was discussed. The PWG agreed that only those hepatocytes with 3 or more nuclei were considered multinucleated; and

1. Minimal is the presence of 1 – 4 multinucleated cells in the sections of liver;
2. Mild is the presence of 4-20 multinucleated cells in the sections of liver; and
3. Moderate is the presence of 20-40 multinucleated cells in the sections of liver.

Eye

There was an increased incidence of corneal mineralization in female mice exposed to 1200 ppm PGMBE compared to control animals. This corneal mineralization occurred along the basement membrane and extended into the corneal stroma. It was often accompanied by chronic active inflammation, fibrosis, and erosion and squamous hyperplasia of the corneal epithelium. While there was good correlation in the diagnosis of this lesion between the SP and QAP, there was only fair correlation between this histologic lesion and the gross finding of "pale foci" on the cornea. The pale foci were seen grossly in 28 high dose female mice, but the mineralization was seen histologically in only 20 out of these 28 mice. The PWG discussed this discrepancy and agreed with the SP's explanation that several pale foci may have been inadvertently missed during the sectioning of the eye.

The PWG reviewed an example of the eye lesion and confirmed the diagnosis of this lesion.

Forestomach

There was a dose-related increased incidence of squamous cell hyperplasia in the forestomach of male mice. The lesion ranged from minimal to moderate and consisted of focal areas of thickening of the epithelium lining the forestomach. The lesion was often accompanied by chronic active inflammation and ulceration. There was no dose-related increase in the severity of the lesion. Further, the PWG discussed that there was no dose related increased incidence of proliferative lesions, such as squamous cell carcinoma or papilloma.

The PWG reviewed an example of squamous hyperplasia with accompanying ulceration and inflammation in a treated male animal and confirmed the diagnosis. The toxicologic significance of this lesion was discussed and the PWG was of the opinion that this lesion is most likely related to the non-specific irritating effects of the chemical following ingestion during grooming. Because the lesion was considered non-specific and due to irritation only, the PWG did not consider the forestomach to be a target organ in this study.

Uterus

The SP reported a statistically significant increase in hydrometra of the uterus in the high dose female mice. Hydrometra was diagnosed when the uterus had a dilated lumen and the lining epithelium was thin and attenuated. The QAP did not agree with the terminology of hydrometra for this change, and classified this change as marked endometrial cystic hyperplasia. The QAP followed the criteria recently set forth in the NTP News Notes.

The PWG reviewed examples of the uterine lesion and concurred with the QAP that those lesions diagnosed as hydrometra by the SP were best referred to as marked cystic endometrial hyperplasia. The PWG also reviewed examples of additional findings of minimal and mild cystic endometrial hyperplasia and were of the unanimous opinion that these additional diagnoses should be made.

Based on their review, the PWG was of the unanimous opinion that there is no treatment-related effect in the uterus. There was a marginal increase in the severity of the cystic hyperplasia in the high dose females when compared to controls, but this increased severity was attributed to biologic variation.

Periodontal Lesion

The SP reported an increased incidence of chronic active inflammation involving the periodontal region near molars in high dose male and female mice. The increased incidence was not accompanied by an increased severity. Examples of this periodontal inflammation were presented to the PWG, and the committee unanimously agreed with the diagnosis and considered this lesion to be of minimal toxicologic significance. The lesion may be secondary to increased grooming of the animal.

Lung

The SP reported an unusual incidence of lung tumors (alveolar bronchiolar adenomas and carcinomas) and alveolar epithelial hyperplasia in male mice exposed to PGMBE. The incidence of neoplasia was 12/50, 10/50, 1/50, and 11/50 in the 0, 75, 300 and 1200 ppm dose groups. The incidence of alveolar bronchiolar hyperplasia was

reported to be 7/50, 4/50, 4/50 and 0/50 in the same dose groups. There was good correlation between pathologists with regards to these proliferative lesions in the lung. Only a few discrepancies between the SP and QAP pathologists were noted and each of these discrepancies were presented to the PWG. These discrepancies were resolved by the consensus of the PWG members. The unusually low incidences of combined adenomas and carcinomas in the 300 ppm males and of alveolar hyperplasia in the 1200 ppm males remains and are of no toxicologic significance in this study.

Harderian Gland

The SP reported an incidence of glandular hyperplasia of the Harderian gland as 10/50, 3/50, 6/50 and 1/50 in the 0, 75, 300 and 1200 ppm dose groups, respectively. There was discrepancy between the SP, QAP and PWG chairperson regarding the diagnosis of four proliferative lesions as hyperplasia in the control males. These four cases were presented to the PWG panel and the consensus of the PWG was that three of these lesions diagnosed originally as hyperplasia by the SP represent adenomas. The PWG panel by consensus determined that the fourth lesion was hyperplasia. The criteria used by the PWG to distinguish adenoma from hyperplasia were those set forth in Maronpot, 1999 (pp. 63, 67). Adenomas generally caused compression of surrounding tissue and distortion of the alveolar glandular architecture.

With the additional diagnoses of Harderian gland adenoma in the three control male mice, the PWG chairperson reviewed all of the Harderian glands in male and female mice from all dose groups. No additional discrepancies were found during this review. The PWG conclusions are 1) there is no treatment-related effect in the Harderian gland; 2) the incidence of Harderian gland adenoma still falls within historical control range (NIEHS, 2000); and 3) any variation in incidence of Harderian gland hyperplasia or adenoma between the control and treatment groups are due to biologic variation.

Small Intestine

The SP reported an incidence of carcinomas in the control female mice at an incidence level of 3/50. This incidence exceeds the historical control range of 0/50 (NIEHS, 2000). There was excellent agreement between the SP and QAP with regards to two of these carcinomas, but there was discrepancy in diagnosis of one of these carcinomas in the control group (Animal number 127). The PWG reviewed this one case of "carcinoma" and determined by consensus that a diagnosis of carcinoma could not be supported. The PWG was of the opinion that the lesion represented glandular hyperplasia.

The PWG also reviewed three other cases where there was a discrepancy of diagnoses between pathologists regarding proliferative lesions in the small intestine. The PWG reviewed each of these cases and resolved the issues by consensus.

The PWG confirmed there is no treatment-related lesion in the small intestine, and variation in the incidence of proliferative lesions in the control and treatment groups is due to biologic variation.

Pituitary Gland

The SP reported an incidence of adenomas of the pars distalis with an incidence of 12/50 or 24% in the control females. This exceeds the historical control range of 0-20% (mean of 7%) (NIEHS, 2000). The PWG reviewed three cases of pars distalis adenomas in the control females and determined by consensus that the diagnosis of adenoma could not be supported. In one case, the lesion was determined by the PWG to represent angiectasis. In another, the PWG decided that the section was inadequate, and in the third case, the PWG was of the opinion that the lesion was more appropriately classified as hyperplasia.

With the PWGs resolution of three discrepancies in the control female pituitary glands, the pars distalis adenomas have an incidence of 9/50 or 18%, which falls within the reported historical control range.

In addition, the PWG reviewed the pituitary of one high dose female animal for which the SP diagnosed a pars distalis adenoma. The PWG determined by consensus that a diagnosis of adenoma could not be supported. The PWG concluded that the lesion represented hyperplasia.

Miscellaneous

The PWG reviewed several cases involving discrepancies of diagnoses between the SP, QAP and/or PWG chairperson. These included:

1. A Zymbal's gland proliferative lesion (Animal 1) that the PWG decided by consensus to represent hyperplasia.
2. A bone lesion (Animal 21) that the PWG decided by consensus to have a fibro-osseous change.
3. A subcutaneous mass (Animal 33) that the PWG decided by consensus to represent hemorrhage rather than hemangiosarcoma.
4. An adrenal medullary lesion (Animal 113) that the PWG concluded to represent adrenal medullary hyperplasia rather than ganglioneuroma;
5. Two uterine lesions involving a discrepancy between angiectasis and hemangiosarcoma. In one case (Animal 506) the PWG decided that angiectasis was the appropriate diagnosis, while in the other case (Animal 534), the PWG decided by consensus that the morphologic changes supported the diagnosis of hemangiosarcoma.

HISTOTECHNIQUE QUALITY

The histotechnique quality assessment indicated that the overall histological processing and slide preparation was good, with no artifacts that would interfere with the interpretation of tissue sections.

Catherine A. Picut, VMD, JD
Diplomate, ACVP
PWG Chairperson

9-12-01
Date

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FINAL#1/RATS

Facility: Battelle Northwest

Chemical CAS #: 57018-52-7

Lock Date: 12/11/00

Cage Range: All

Reasons For Removal: All

Removal Date Range: All

Treatment Groups: Include All

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FISCHER 344 RATS FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
DISPOSITION SUMMARY				
Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	14	12	20	11
Natural Death	3	4	2	3
Survivors				
Terminal Sacrifice	33	34	28	36
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Liver	(49)	(50)	(50)	(50)
Angiectasis	1 [3.0]		3 [2.3]	1 [2.0]
Basophilic Focus	2	20	12	14
Clear Cell Focus	12	13	11	27
Eosinophilic Focus	1			1
Fatty Change		1 [2.0]		
Hepatodiaphragmatic Nodule	8 [4.0]	10 [4.0]	9 [3.7]	7 [4.0]
Infarct	1 [4.0]			
Inflammation, Granulomatous	1 [2.0]		1 [3.0]	2 [1.5]
Necrosis		1 [4.0]	1 [4.0]	2 [3.0]
Thrombosis				1 [4.0]
Vacuolization Cytoplasmic	3 [2.7]	4 [3.3]	3 [4.0]	
Bile Duct, Dilatation	1 [4.0]			
Serosa, Hemorrhage	1 [3.0]			
Mesentery	(17)	(23)	(10)	(17)
Necrosis	17 [2.5]	21 [2.7]	9 [2.3]	17 [2.4]
Fat, Hemorrhage	1 [3.0]	1 [3.0]		
Pancreas	(49)	(50)	(50)	(50)
Cyst			1 [4.0]	
Necrosis		1 [4.0]		
Stomach, Forestomach	(49)	(50)	(50)	(49)
Erosion				1 [2.0]
Inflammation, Suppurative			1 [3.0]	
Ulcer			4 [4.0]	
Stomach, Glandular	(49)	(50)	(50)	(49)
Ulcer	1 [4.0]			
Epithelium, Hyperplasia				1 [2.0]
Tongue	(2)			(1)
Epithelium, Hyperkeratosis				1 [1.0]
Epithelium, Hyperplasia	1 [2.0]			

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FISCHER 344 RATS FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
ALIMENTARY SYSTEM - CONT				
Tooth	(1)			
Peridontal Tissue, Inflammation	1 [3.0]			
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy		3 [2.7]	1 [2.0]	
Atrium, Thrombosis		2 [4.0]		
Epicardium, Inflammation, Chronic			1 [4.0]	
Myocardium, Degeneration			1 [3.0]	
Myocardium, Necrosis			1 [2.0]	
ENDOCRINE SYSTEM				
Adrenal Cortex	(49)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule				1 [3.0]
Atrophy		1 [4.0]		
Degeneration, Cystic	1 [4.0]			
Hemorrhage			1 [2.0]	
Hyperplasia	2 [2.0]		2 [2.0]	1 [2.0]
Metaplasia, Osseous	1 [3.0]			
Vacuolization Cytoplasmic	15 [2.2]	10 [2.5]	6 [2.0]	5 [2.0]
Adrenal Medulla	(49)	(50)	(50)	(50)
Hyperplasia	1 [4.0]	1 [2.0]	2 [3.5]	
Pituitary Gland	(49)	(50)	(50)	(49)
Angiectasis	4 [3.3]	4 [2.3]	1 [2.0]	4 [3.3]
Cyst				1 [4.0]
Hemorrhage	1 [4.0]		1 [4.0]	
Hyperplasia	3 [3.0]	6 [2.8]	3 [2.7]	3 [3.3]
Pars Intermedia, Vacuolization Cytoplasmic				1 [2.0]
Thyroid Gland	(49)	(50)	(50)	(50)
C-Cell, Hyperplasia	9 [1.4]	8 [2.1]	7 [2.6]	5 [2.0]
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FISCHER 344 RATS FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
GENITAL SYSTEM - CONT				
Clitoral Gland	(50)	(50)	(50)	(50)
Cyst	2 [3.0]	3 [4.0]	1 [1.0]	4 [4.0]
Hyperplasia	3 [2.7]	3 [4.0]	2 [3.5]	2 [3.5]
Inflammation, Chronic		1 [3.0]	2 [4.0]	1 [2.0]
Ovary	(50)	(50)	(50)	(50)
Cyst	6 [2.8]	5 [4.0]	3 [3.7]	8 [3.3]
Hemorrhage			1 [3.0]	
Uterus	(50)	(50)	(50)	(50)
Decidual Reaction	1 [4.0]			
Hemorrhage	1 [4.0]			1 [4.0]
Hemorrhage, Chronic	1 [4.0]			
Necrosis			1 [4.0]	
Endometrium, Hyperplasia			1 [2.0]	2 [3.0]
Endometrium, Ulcer				1 [1.0]
HEMATOPOIETIC SYSTEM				
Lymph Node	(5)	(3)	(3)	(6)
Deep Cervical, Infiltration Cellular, Histiocyte			1 [2.0]	
Deep Cervical, Inflammation, Chronic	1 [4.0]			
Lymph Node, Bronchial	(9)	(4)	(10)	(5)
Angiectasis	1 [3.0]			1 [3.0]
Infiltration Cellular, Histiocyte			1 [3.0]	
Lymph Node, Mandibular	(1)	(2)	(2)	
Ectasia		1 [4.0]	1 [4.0]	
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Fibrosis		1 [3.0]		
Hemorrhage		1 [3.0]		
Lymph Node, Mediastinal	(43)	(46)	(45)	(43)
Angiectasis	3 [3.0]	1 [4.0]	1 [4.0]	2 [3.5]
Fibrosis		1 [3.0]	1 [2.0]	
Hemorrhage		1 [3.0]		
Infiltration Cellular, Histiocyte	1 [3.0]	2 [3.0]	4 [3.5]	
Inflammation, Suppurative			1 [2.0]	
Pigmentation	3 [2.7]	1 [3.0]		
Spleen	(49)	(50)	(50)	(50)
Accessory Spleen	1 [0.0]	2 [3.0]		
Degeneration		1 [1.0]		
Fibrosis				2 [3.5]
Hematopoietic Cell Proliferation				1 [4.0]
Hemorrhage	1 [4.0]			

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FISCHER 344 RATS FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
HEMATOPOIETIC SYSTEM - CONT				
Necrosis		1 [4.0]		3 [3.7]
INTEGUMENTARY SYSTEM				
Mammary Gland	(49)	(50)	(50)	(50)
Galactocele		7 [4.0]	2 [4.0]	1 [4.0]
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion		1 [4.0]	1 [4.0]	
Hyperkeratosis			1 [1.0]	
Inflammation, Chronic		1 [4.0]	1 [3.0]	1 [2.0]
Ulcer	1 [3.0]			1 [4.0]
Subcutaneous Tissue, Hemorrhage				1 [1.0]
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Fibrous Osteodystrophy		1 [3.0]		
Maxilla, Necrosis	1 [4.0]			
Metatarsal, Fracture				1 [3.0]
Tibia, Osteopetrosis		1 [3.0]		
NERVOUS SYSTEM				
Brain	(49)	(50)	(50)	(50)
Compression	5 [3.3]	9 [3.0]	8 [3.0]	4 [2.8]
Hemorrhage	4 [3.0]	3 [2.3]	6 [3.8]	2 [3.0]
Hydrocephalus		1 [3.0]		
Medulla, Gliosis, Focal			1 [3.0]	
RESPIRATORY SYSTEM				
Larynx	(49)	(50)	(50)	(50)
Foreign Body	1 [4.0]	1 [4.0]		
Inflammation, Suppurative	4 [2.3]	2 [1.5]	1 [2.0]	2 [2.0]
Epiglottis, Metaplasia, Squamous			1 [2.0]	2 [1.5]
Respiratory Epithelium, Epiglottis, Degeneration			1 [1.0]	
Lung	(50)	(50)	(50)	(50)
Foreign Body				1 [3.0]

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FISCHER 344 RATS FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
RESPIRATORY SYSTEM - CONT				
Hemorrhage	1 [4.0]	2 [2.0]		1 [3.0]
Inflammation, Chronic	9 [1.3]	2 [1.0]	7 [1.4]	6 [1.7]
Metaplasia, Osseous			1 [1.0]	
Thrombosis	1 [2.0]			
Alveolar Epithelium, Hyperplasia	6 [3.0]	4 [1.5]	5 [1.6]	4 [2.3]
Alveolus, Infiltration Cellular, Histiocyte	15 [1.4]	9 [1.0]	13 [1.5]	20 [1.6]
Alveolus, Proteinosis	4 [1.5]		3 [1.0]	2 [1.0]
Bronchiole, Hyperplasia	1 [2.0]	1 [1.0]		
Interstitium, Fibrosis	4 [1.0]	1 [2.0]	4 [2.3]	2 [2.0]
Mediastinum, Inflammation, Granulomatous			1 [2.0]	
Nose	(49)	(49)	(50)	(50)
Foreign Body	2 [3.0]	2 [3.0]	2 [3.0]	
Inflammation, Suppurative	4 [2.5]	2 [2.5]	5 [2.8]	
Glands, Dilatation				4 [1.5]
Goblet Cell, Hyperplasia				3 [1.7]
Nasolacrimal Duct, Inflammation, Suppurative	1 [2.0]	1 [2.0]	4 [2.8]	1 [3.0]
Olfactory Epithelium, Degeneration, Hyaline	10 [1.9]	22 [2.0]	48 [2.3]	50 [3.6]
Respiratory Epithelium, Hyperplasia	2 [2.5]	1 [2.0]	1 [2.0]	1 [1.0]
Pleura	(50)	(50)	(49)	(50)
Inflammation, Chronic	15 [1.5]	10 [1.0]	11 [1.7]	17 [1.4]
SPECIAL SENSES SYSTEM				
Eye	(49)	(50)	(50)	(50)
Atrophy			2 [4.0]	
Phthisis Bulbi	1		1	
Anterior Chamber, Sclera, Inflammation, Suppurative			1 [4.0]	
Cornea, Edema				1 [3.0]
Cornea, Inflammation, Chronic			1 [1.0]	1 [2.0]
Cornea, Mineralization				10 [1.5]
Cornea, Necrosis				1 [2.0]
Lens, Cataract	1 [3.0]	4 [3.3]	3 [3.3]	1 [3.0]
Lens, Mineralization		1 [4.0]		
Sclera, Inflammation, Suppurative	1 [4.0]			
Zymbal's Gland	(42)	(44)	(43)	(46)
Cyst			1 [2.0]	
Hyperplasia			1 [2.0]	
URINARY SYSTEM				

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FISCHER 344 RATS FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
URINARY SYSTEM - CONT				
Kidney	(49)	(50)	(50)	(50)
Inflammation, Suppurative		2 [4.0]		
Nephropathy, Chronic	45 [1.5]	45 [1.6]	45 [1.7]	49 [2.1]
Cortex, Infarct				1 [4.0]
Cortex, Renal Tubule, Accumulation, Hyaline Droplet	1 [4.0]	2 [3.5]		1 [4.0]
Cortex, Renal Tubule, Hyperplasia			1 [4.0]	1 [1.0]
Pelvis, Mineralization	13 [1.1]	5 [1.0]	7 [1.0]	3 [1.0]
Pelvis, Transitional Epithelium, Hyperplasia		4 [1.3]		
Renal Tubule, Mineralization			2 [2.5]	
Urethra				(1)
Transitional Epithelium, Hyperplasia				1 [3.0]
Urinary Bladder	(49)	(50)	(50)	(50)
Hemorrhage	1 [3.0]			
Mineralization			1 [2.0]	
Ulcer			1 [3.0]	
Transitional Epithelium, Hyperplasia	1 [1.0]	1 [3.0]		
Transitional Epithelium, Mineralization			1 [3.0]	

a Number of animals examined microscopically at site and number of animals with lesion
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FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
DISPOSITION SUMMARY				
Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	20	15	26	22
Natural Death	3	6	8	6
Survivors				
Terminal Sacrifice	27	29	16	22
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Large, Rectum	(50)	(48)	(47)	(48)
Diverticulum	1			
Intestine Large, Cecum	(47)	(47)	(47)	(45)
Hemorrhage			1 [4.0]	
Necrosis		1 [4.0]		
Intestine Small, Duodenum	(48)	(47)	(47)	(47)
Epithelium, Hyperplasia				1 [3.0]
Intestine Small, Jejunum	(47)	(47)	(42)	(46)
Epithelium, Hyperplasia				1 [3.0]
Intestine Small, Ileum	(47)	(47)	(43)	(45)
Epithelium, Hyperplasia				1 [3.0]
Liver	(50)	(50)	(49)	(50)
Basophilic Focus	2		1	8
Clear Cell Focus	8	11	11	9
Degeneration, Cystic	1 [3.0]		1 [4.0]	3 [3.0]
Eosinophilic Focus		1	1	2
Fatty Change	3 [2.0]			1 [2.0]
Hepatodiaphragmatic Nodule	1 [4.0]	6 [4.0]	11 [4.0]	5 [4.0]
Necrosis			3 [4.0]	1 [4.0]
Thrombosis	1 [4.0]			
Vacuolization Cytoplasmic	3 [3.0]	1 [4.0]	2 [4.0]	1 [4.0]
Bile Duct, Cyst	1 [4.0]			
Bile Duct, Dilatation			1 [4.0]	
Bile Duct, Hyperplasia			1 [3.0]	1 [3.0]
Hepatocyte, Regeneration			1 [4.0]	
Mesentery	(13)	(9)	(10)	(7)
Necrosis	13 [2.4]	9 [2.4]	10 [2.4]	5 [2.8]
Thrombosis				1 [4.0]
Fat, Hemorrhage		1 [3.0]		
Oral Mucosa		(1)		

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INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
ALIMENTARY SYSTEM - CONT				
Ulcer		1 [4.0]		
Pancreas	(50)	(50)	(49)	(50)
Acinus, Atrophy		1 [4.0]	1 [4.0]	
Artery, Inflammation				1 [3.0]
Stomach, Forestomach	(50)	(50)	(49)	(50)
Hyperplasia, Squamous	2 [2.5]	1 [2.0]	2 [2.0]	4 [3.5]
Inflammation, Suppurative	1 [3.0]			
Necrosis			1 [1.0]	
Ulcer	3 [3.7]		3 [4.0]	4 [4.0]
Stomach, Glandular	(50)	(50)	(49)	(50)
Erosion			3 [3.3]	
Mineralization			1 [2.0]	
Necrosis	1 [3.0]			1 [3.0]
Ulcer			1 [4.0]	
Epithelium, Hyperplasia				1 [1.0]
Tongue	(2)		(3)	(1)
Epithelium, Hyperplasia	2 [3.5]		3 [3.0]	1 [4.0]
Tooth	(1)	(2)		(1)
Malformation		1 [4.0]		
Peridontal Tissue, Inflammation	1 [3.0]	1 [4.0]		1 [3.0]
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(49)	(50)
Pulmonary Artery, Degeneration, Mucoid			1 [4.0]	
Heart	(50)	(50)	(49)	(50)
Cardiomyopathy	7 [2.1]	6 [1.8]	4 [2.8]	7 [2.0]
Inflammation, Focal, Suppurative			1 [4.0]	
Atrium, Thrombosis	1 [4.0]		1 [3.0]	
Myocardium, Fibrosis		1 [4.0]		
Myocardium, Necrosis	1 [3.0]			
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(49)	(50)
Hyperplasia		1 [2.0]		3 [2.3]
Mineralization			1 [2.0]	
Necrosis	1 [2.0]			
Vacuolization Cytoplasmic	6 [1.8]	14 [1.9]	6 [2.3]	9 [2.4]
Adrenal Medulla	(50)	(50)	(49)	(50)
Hyperplasia	6 [2.0]	4 [3.8]	11 [2.6]	9 [3.2]

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
ENDOCRINE SYSTEM - CONT				
Thrombosis			1 [4.0]	
Islets, Pancreatic	(50)	(50)	(49)	(50)
Hyperplasia			1 [4.0]	1 [4.0]
Parathyroid Gland	(49)	(49)	(48)	(49)
Hyperplasia	1 [3.0]			
Pituitary Gland	(50)	(50)	(49)	(50)
Angiectasis	1 [2.0]	3 [3.7]	1 [1.0]	
Atrophy				1 [4.0]
Cyst		1 [4.0]		
Hemorrhage	1 [4.0]	1 [4.0]	2 [4.0]	
Hyperplasia	5 [2.8]	2 [3.0]	4 [3.8]	2 [3.0]
Thyroid Gland	(50)	(50)	(49)	(50)
C-Cell, Hyperplasia	8 [1.4]	4 [1.5]	7 [1.1]	7 [1.9]
Follicular Cell, Hyperplasia	1 [1.0]	1 [3.0]		
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Penis			(1)	
Necrosis			1 [4.0]	
Preputial Gland	(50)	(50)	(49)	(50)
Hyperplasia	2 [3.5]	3 [3.3]	3 [3.7]	
Inflammation, Suppurative	4 [3.3]		4 [4.0]	
Prostate	(50)	(50)	(49)	(50)
Hyperplasia	1 [2.0]	1 [2.0]		1 [2.0]
Inflammation, Suppurative	31 [1.7]	24 [1.8]	27 [2.1]	27 [1.7]
Seminal Vesicle	(50)	(50)	(49)	(50)
Dilatation		1 [3.0]		
Inflammation, Suppurative	1 [4.0]			
Epithelium, Hyperplasia	1 [3.0]			
Testes	(50)	(50)	(49)	(50)
Bilateral, Interstitial Cell, Hyperplasia			1 [3.0]	1 [3.0]
Germinal Epithelium, Atrophy	20 [2.5]	19 [2.4]	18 [2.8]	20 [3.4]
Interstitial Cell, Hyperplasia	4 [3.0]	3 [3.0]	7 [3.0]	7 [3.0]
HEMATOPOIETIC SYSTEM				

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
HEMATOPOIETIC SYSTEM - CONT				
Lymph Node	(12)	(7)	(15)	(6)
Deep Cervical, Ectasia		1 [3.0]		
Deep Cervical, Hyperplasia, Lymphoid	1 [3.0]			
Deep Cervical, Inflammation		1 [4.0]		
Deep Cervical, Inflammation, Suppurative				1 [4.0]
Pancreatic, Ectasia	1 [4.0]			
Pancreatic, Hemorrhage			1 [4.0]	
Pancreatic, Pigmentation		1 [3.0]		
Lymph Node, Bronchial	(24)	(7)	(9)	(21)
Hemorrhage			1 [4.0]	
Hyperplasia, Lymphoid				2 [3.0]
Lymph Node, Mesenteric	(50)	(50)	(49)	(50)
Ectasia		1 [3.0]		
Fibrosis				1 [2.0]
Lymph Node, Mediastinal	(38)	(41)	(46)	(45)
Angiectasis		1 [3.0]	1 [4.0]	
Hyperplasia, Lymphoid	1 [3.0]	1 [2.0]		
Spleen	(50)	(50)	(49)	(50)
Accessory Spleen	2	3	4	1
Fibrosis	5 [2.4]	1 [2.0]	7 [3.3]	4 [2.8]
Hemorrhage	1 [4.0]		1 [4.0]	3 [4.0]
Necrosis	1 [4.0]	2 [4.0]	5 [3.6]	1 [3.0]
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(49)	(50)
Galactocele	3 [3.7]	2 [4.0]	2 [4.0]	1 [4.0]
Metaplasia, Squamous		1 [3.0]		
Epithelium, Cyst, Squamous				1 [4.0]
Skin	(50)	(50)	(49)	(50)
Cyst Epithelial Inclusion	3 [4.0]	5 [4.0]	3 [4.0]	1 [4.0]
Hyperkeratosis	3 [3.3]	1 [4.0]	6 [3.3]	1 [3.0]
Inflammation, Granulomatous				2 [3.0]
Ulcer	1 [2.0]			2 [3.5]
Prepuce, Ulcer			1 [4.0]	
Sebaceous Gland, Hyperplasia, Squamous	1 [3.0]			
Subcutaneous Tissue, Hemorrhage				1 [2.0]
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(49)	(50)

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
MUSCULOSKELETAL SYSTEM - CONT				
Fibrous Osteodystrophy	1 [3.0]			
Cranium, Hemorrhage				1 [4.0]
Skeletal Muscle			(2)	(3)
Mineralization				1 [2.0]
NERVOUS SYSTEM				
Brain	(50)	(50)	(49)	(50)
Compression	7 [3.0]	4 [3.0]	5 [2.3]	3 [3.7]
Gliosis			1 [3.0]	
Hemorrhage	4 [3.5]	4 [2.5]	4 [3.0]	2 [3.5]
RESPIRATORY SYSTEM				
Larynx	(50)	(49)	(48)	(50)
Foreign Body	1 [4.0]	2 [4.0]	1 [4.0]	1 [4.0]
Inflammation, Chronic	1 [1.0]			3 [2.0]
Inflammation, Suppurative		2 [3.5]	1 [1.0]	
Epiglottis, Hyperplasia		1 [2.0]	1 [2.0]	1 [2.0]
Epiglottis, Metaplasia, Squamous			1 [2.0]	
Lung	(50)	(50)	(49)	(50)
Hemorrhage	1 [2.0]	2 [3.0]	1 [2.0]	1 [2.0]
Inflammation, Chronic	5 [1.2]	2 [2.0]	5 [1.6]	4 [1.5]
Inflammation, Suppurative			1 [4.0]	2 [3.5]
Necrosis, Focal	1 [4.0]			
Alveolar Epithelium, Hyperplasia	6 [1.3]	2 [3.5]	5 [1.8]	6 [3.5]
Alveolar Epithelium, Metaplasia, Squamous	1 [1.0]			4 [3.3]
Alveolus, Foreign Body				2 [3.0]
Alveolus, Infiltration Cellular, Histiocyte	11 [1.8]	3 [2.0]	8 [2.0]	8 [1.8]
Alveolus, Proteinosis		1 [2.0]		
Artery, Mineralization			1 [4.0]	
Artery, Thrombosis			1 [4.0]	
Interstitium, Fibrosis	5 [1.6]	1 [2.0]	4 [2.0]	6 [1.8]
Nose	(50)	(49)	(49)	(50)
Foreign Body	6 [3.0]	6 [3.2]	4 [3.0]	3 [3.0]
Hemorrhage				1 [4.0]
Inflammation, Chronic				4 [1.5]
Inflammation, Suppurative	6 [1.7]	10 [2.2]	11 [2.2]	4 [2.5]
Glands, Dilatation	1 [2.0]	2 [1.0]	7 [1.9]	15 [1.8]
Goblet Cell, Hyperplasia	1 [1.0]	1 [1.0]	2 [2.5]	15 [1.9]
Nasolacrimal Duct, Inflammation, Suppurative		1 [2.0]		1 [2.0]

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
RESPIRATORY SYSTEM - CONT				
Olfactory Epithelium, Degeneration, Hyaline		25 [1.8]	45 [3.0]	50 [3.6]
Olfactory Epithelium, Hyperplasia, Basal Cell				1 [3.0]
Respiratory Epithelium, Hyperplasia	2 [2.0]	2 [1.5]	4 [2.3]	3 [2.3]
Respiratory Epithelium, Metaplasia, Squamous			1 [2.0]	
Pleura	(49)	(50)	(49)	(50)
Inflammation, Chronic	6 [1.5]	2 [2.0]	3 [1.3]	7 [1.3]
Mesothelium, Hyperplasia				2 [2.0]
Trachea	(50)	(49)	(49)	(50)
Glands, Cyst			1 [3.0]	
SPECIAL SENSES SYSTEM				
Ear		(1)		(1)
Cyst		1 [4.0]		
Eye	(50)	(49)	(49)	(50)
Atrophy				1 [4.0]
Hemorrhage	1 [4.0]			
Anterior Chamber, Inflammation, Suppurative			1 [3.0]	
Anterior Chamber, Cornea, Inflammation				1 [2.0]
Anterior Chamber, Cornea, Inflammation, Suppurative				1 [3.0]
Cornea, Inflammation, Suppurative			1 [2.0]	
URINARY SYSTEM				
Kidney	(50)	(50)	(49)	(50)
Infarct		1 [4.0]		
Nephropathy, Chronic	46 [1.9]	50 [2.3]	49 [2.9]	50 [3.5]
Pigmentation			1 [2.0]	
Cortex, Infarct	4 [3.3]			2 [3.5]
Cortex, Renal Tubule, Accumulation, Hyaline Droplet	1 [3.0]	2 [3.0]	9 [3.1]	17 [2.6]
Cortex, Renal Tubule, Hyperplasia		3 [2.3]	7 [2.7]	19 [2.4]
Cortex, Renal Tubule, Necrosis			1 [3.0]	
Papilla, Mineralization		8 [1.0]	28 [1.6]	41 [1.0]
Pelvis, Dilatation	1 [4.0]			
Pelvis, Inflammation, Suppurative			1 [2.0]	
Pelvis, Transitional Epithelium, Hyperplasia	2 [1.0]	1 [1.0]	6 [1.3]	15 [1.4]
Renal Tubule, Mineralization	1 [3.0]			
Renal Tubule, Pigmentation	1 [3.0]		2 [4.0]	
Urethra	(1)		(1)	(2)

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
URINARY SYSTEM - CONT				
Inflammation, Suppurative				1 [3.0]
Transitional Epithelium, Hyperplasia	1 [2.0]		1 [4.0]	2 [3.0]
Urinary Bladder	(50)	(49)	(49)	(50)
Hemorrhage	1 [4.0]			
Inflammation, Chronic	1 [2.0]			
Inflammation, Suppurative	1 [4.0]			
Necrosis	1 [4.0]			
Ulcer	1 [4.0]			
Transitional Epithelium, Hyperplasia	3 [1.7]	1 [3.0]	3 [2.3]	6 [1.7]

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

---------- END OF REPORT ----------

FINAL#1/RATS

Facility: Battelle Northwest

Chemical CAS #: 57018-52-7

Lock Date: 12/11/00

Cage Range: All

Reasons For Removal: All

Removal Date Range: All

Treatment Groups: Include All

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

FISCHER 344 RATS FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
DISPOSITION SUMMARY				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	14	12	20	11
Natural Death	3	4	2	3
Survivors				
Terminal Sacrifice	33	34	28	36
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Liver	(49)	(50)	(50)	(50)
Hepatocellular Adenoma	1 (2%)			2 (4%)
Histiocytic Sarcoma, Metastatic, Skin				1 (2%)
Mesentery	(17)	(23)	(10)	(17)
Carcinoma, Metastatic, Ovary			1 (10%)	
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
Adrenal Cortex	(49)	(50)	(50)	(50)
Adenoma	2 (4%)	2 (4%)	1 (2%)	4 (8%)
Carcinoma		2 (4%)		1 (2%)
Adrenal Medulla	(49)	(50)	(50)	(50)
Pheochromocytoma Malignant				1 (2%)
Pheochromocytoma Benign	2 (4%)	1 (2%)		
Islets, Pancreatic	(49)	(50)	(50)	(50)
Adenoma		1 (2%)	1 (2%)	2 (4%)
Carcinoma	1 (2%)			
Pituitary Gland	(49)	(50)	(50)	(49)
Adenoma	30 (61%)	36 (72%)	32 (64%)	22 (45%)
Carcinoma, Metastatic, Zymbal's Gland	1 (2%)			
Thyroid Gland	(49)	(50)	(50)	(50)
C-Cell, Adenoma	8 (16%)	2 (4%)	3 (6%)	4 (8%)
C-Cell, Carcinoma	2 (4%)			

FISCHER 344 RATS FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
ENDOCRINE SYSTEM - cont				
Follicular Cell, Adenoma		1 (2%)		
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Carcinoma	2 (4%)	2 (4%)	1 (2%)	
Sarcoma, Metastatic, Vagina	1 (2%)			
Ovary	(50)	(50)	(50)	(50)
Cystadenocarcinoma		1 (2%)	1 (2%)	
Granulosa Cell Tumor Malignant			1 (2%)	
Granulosa-Theca Tumor Malignant	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Leiomyosarcoma	1 (2%)			
Polyp Stromal	5 (10%)	7 (14%)	11 (22%)	6 (12%)
Sarcoma Stromal			1 (2%)	
Bilateral, Polyp Stromal			1 (2%)	
Endometrium, Adenoma		1 (2%)		
Vagina	(1)			
Sarcoma	1 (100%)			
HEMATOPOIETIC SYSTEM				
Lymph Node	(5)	(3)	(3)	(6)
Lymph Node, Bronchial	(9)	(4)	(10)	(5)
Histiocytic Sarcoma, Metastatic, Skin				1 (20%)
Squamous Cell Carcinoma, Metastatic, Lung			1 (10%)	
Lymph Node, Mandibular	(1)	(2)	(2)	
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Lymph Node, Mediastinal	(43)	(46)	(45)	(43)
Histiocytic Sarcoma, Metastatic, Skin				1 (2%)
Squamous Cell Carcinoma, Metastatic, Lung			2 (4%)	
Spleen	(49)	(50)	(50)	(50)
Thymus	(45)	(50)	(50)	(48)

FISCHER 344 RATS FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
INTEGUMENTARY SYSTEM				
Mammary Gland	(49)	(50)	(50)	(50)
Adenoma		2 (4%)		
Carcinoma	4 (8%)	4 (8%)	1 (2%)	1 (2%)
Carcinoma, Multiple	1 (2%)			
Fibroadenoma	18 (37%)	21 (42%)	17 (34%)	20 (40%)
Fibroadenoma, Multiple	7 (14%)	8 (16%)	4 (8%)	9 (18%)
Sarcoma, Metastatic, Vagina	1 (2%)			
Skin	(50)	(50)	(50)	(50)
Squamous Cell Papilloma				1 (2%)
Eyelid, Neural Crest Tumor			1 (2%)	
Subcutaneous Tissue, Fibroma	1 (2%)			
Subcutaneous Tissue, Fibrosarcoma	1 (2%)			1 (2%)
Subcutaneous Tissue, Fibrous Histiocytoma	1 (2%)			
Subcutaneous Tissue, Histiocytic Sarcoma				1 (2%)
Subcutaneous Tissue, Lipoma			1 (2%)	
Subcutaneous Tissue, Liposarcoma	1 (2%)			
Subcutaneous Tissue, Sarcoma, Metastatic, Vagina	1 (2%)			
MUSCULOSKELETAL SYSTEM				
Skeletal Muscle	(1)		(2)	
Fibrous Histiocytoma, Metastatic, Skin	1 (100%)			
Squamous Cell Carcinoma, Metastatic, Lung			1 (50%)	
NERVOUS SYSTEM				
Brain	(49)	(50)	(50)	(50)
Carcinoma, Metastatic, Zymbal's Gland	1 (2%)			
Pineal Gland, Carcinoma			1 (2%)	
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Thyroid Gland	1 (2%)			
Carcinoma, Metastatic, Adrenal Cortex		1 (2%)		
Histiocytic Sarcoma, Metastatic, Skin				1 (2%)
Sarcoma, Metastatic, Vagina	1 (2%)			
Squamous Cell Carcinoma			2 (4%)	

FISCHER 344 RATS FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
RESPIRATORY SYSTEM - cont				
Alveolus, Squamous Cell Carcinoma, Metastatic, Lung			1 (2%)	
SPECIAL SENSES SYSTEM				
Zymbal's Gland	(42)	(44)	(43)	(46)
Carcinoma	2 (5%)	1 (2%)	1 (2%)	
URINARY SYSTEM				
Kidney	(49)	(50)	(50)	(50)
Cortex, Renal Tubule, Adenoma				1 (2%)
Urinary Bladder	(49)	(50)	(50)	(50)
Transitional Epithelium, Papilloma				1 (2%)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma				1 (2%)
Leukemia Mononuclear	24 (48%)	24 (48%)	28 (56%)	20 (40%)

* Number of animals with any tissue examined microscopically

FISCHER 344 RATS FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
TUMOR SUMMARY				
Total Animals with Primary Neoplasms (b)	49	48	50	45
Total Primary Neoplasms	117	116	109	97
Total Animals with Benign Neoplasms	41	45	42	41
Total Benign Neoplasms	75	82	71	72
Total Animals with Malignant Neoplasms	33	27	32	23
Total Malignant Neoplasms	42	34	37	25
Total Animals with Metastatic Neoplasms	4	1	3	1
Total Metastatic Neoplasm	8	1	6	4
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain-Benign or Malignant			1	
Total Uncertain Neoplasms			1	

a Number of animals examined microscopically at site and number of animals with lesion
b Primary tumors: all tumors except metastatic tumors

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
DISPOSITION SUMMARY				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	20	15	26	22
Natural Death	3	6	8	6
Survivors				
Terminal Sacrifice	27	29	16	22
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(49)	(50)
Carcinoma, Metastatic, Thyroid Gland				1 (2%)
Intestine Large, Colon	(49)	(48)	(46)	(48)
Polyp Adenomatous	1 (2%)			
Intestine Large, Cecum	(47)	(47)	(47)	(45)
Intestine Small, Ileum	(47)	(47)	(43)	(45)
Liver	(50)	(50)	(49)	(50)
Cholangiocarcinoma				1 (2%)
Hepatocellular Adenoma	3 (6%)		2 (4%)	6 (12%)
Histiocytic Sarcoma, Metastatic, Skin		1 (2%)		
Mesentery	(13)	(9)	(10)	(7)
Stomach, Forestomach	(50)	(50)	(49)	(50)
Stomach, Glandular	(50)	(50)	(49)	(50)
Carcinoma				1 (2%)
Muscularis, Lipoma	1 (2%)			
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(49)	(50)
Aorta, Pulmonary Artery, Sarcoma, Metastatic, Heart				1 (2%)
Heart	(50)	(50)	(49)	(50)
Carcinoma, Metastatic, Lung				1 (2%)
Pericardium, Sarcoma				1 (2%)

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
ENDOCRINE SYSTEM				
Adrenal Medulla	(50)	(50)	(49)	(50)
Pheochromocytoma Malignant	2 (4%)			2 (4%)
Pheochromocytoma Complex		1 (2%)		
Pheochromocytoma Benign	10 (20%)	8 (16%)	8 (16%)	6 (12%)
Bilateral, Pheochromocytoma Benign	2 (4%)		3 (6%)	1 (2%)
Islets, Pancreatic	(50)	(50)	(49)	(50)
Adenoma	4 (8%)	4 (8%)	5 (10%)	
Carcinoma			1 (2%)	1 (2%)
Parathyroid Gland	(49)	(49)	(48)	(49)
Carcinoma, Metastatic, Thyroid Gland				2 (4%)
Pituitary Gland	(50)	(50)	(49)	(50)
Adenoma	35 (70%)	27 (54%)	26 (53%)	32 (64%)
Thyroid Gland	(50)	(50)	(49)	(50)
C-Cell, Adenoma	3 (6%)	3 (6%)	3 (6%)	5 (10%)
C-Cell, Adenoma, Multiple		1 (2%)		
C-Cell, Carcinoma	1 (2%)	1 (2%)	3 (6%)	3 (6%)
Follicular Cell, Adenoma		1 (2%)		1 (2%)
Follicular Cell, Carcinoma	1 (2%)			1 (2%)
GENERAL BODY SYSTEM				
Peritoneum		(1)	(2)	(2)
GENITAL SYSTEM				
Epididymis	(50)	(50)	(49)	(50)
Preputial Gland	(50)	(50)	(49)	(50)
Adenoma	1 (2%)			
Carcinoma	1 (2%)	2 (4%)	1 (2%)	2 (4%)
Prostate	(50)	(50)	(49)	(50)
Seminal Vesicle	(50)	(50)	(49)	(50)
Testes	(50)	(50)	(49)	(50)
Bilateral, Interstitial Cell, Adenoma	29 (58%)	31 (62%)	30 (61%)	32 (64%)
Interstitial Cell, Adenoma	12 (24%)	14 (28%)	10 (20%)	10 (20%)

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(49)	(50)
Lymph Node	(12)	(7)	(15)	(6)
Deep Cervical, Carcinoma, Metastatic, Thyroid Gland		1 (14%)		
Lymph Node, Bronchial	(24)	(7)	(9)	(21)
Carcinoma, Metastatic, Lung				1 (5%)
Histiocytic Sarcoma, Metastatic, Skin		1 (14%)		
Lymph Node, Mandibular	(1)	(3)	(3)	(1)
Carcinoma, Metastatic, Zymbal's Gland		1 (33%)		
Lymph Node, Mesenteric	(50)	(50)	(49)	(50)
Lymph Node, Mediastinal	(38)	(41)	(46)	(45)
Carcinoma, Metastatic, Lung				1 (2%)
Carcinoma, Metastatic, Zymbal's Gland		1 (2%)		
Histiocytic Sarcoma, Metastatic, Skin		1 (2%)		
Sarcoma, Metastatic, Heart				1 (2%)
Spleen	(50)	(50)	(49)	(50)
Thymus	(47)	(46)	(46)	(47)
Sarcoma, Metastatic, Heart				1 (2%)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(49)	(50)
Carcinoma		2 (4%)	2 (4%)	1 (2%)
Fibroadenoma	2 (4%)	2 (4%)	3 (6%)	3 (6%)
Skin	(50)	(50)	(49)	(50)
Basal Cell Adenoma		1 (2%)		3 (6%)
Basal Cell Carcinoma				1 (2%)
Keratoacanthoma	1 (2%)			
Squamous Cell Papilloma	1 (2%)		1 (2%)	1 (2%)
Pinna, Neural Crest Tumor		1 (2%)		
Sebaceous Gland, Adenoma	1 (2%)			
Subcutaneous Tissue, Fibroma	2 (4%)	4 (8%)	2 (4%)	4 (8%)
Subcutaneous Tissue, Fibrosarcoma	1 (2%)			
Subcutaneous Tissue, Histiocytic Sarcoma		1 (2%)		
Subcutaneous Tissue, Lipoma	1 (2%)	2 (4%)	1 (2%)	
Subcutaneous Tissue, Sarcoma				1 (2%)
Subcutaneous Tissue, Schwannoma Benign				1 (2%)

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(49)	(50)
Mandible, Carcinoma, Metastatic, Zymbal's Gland		1 (2%)		
Mandible, Osteosarcoma	1 (2%)			
Vertebra, Chordoma			1 (2%)	
Skeletal Muscle			(2)	(3)
Carcinoma, Metastatic, Thyroid Gland			1 (50%)	
Sarcoma, Metastatic, Skin				1 (33%)
NERVOUS SYSTEM				
Brain	(50)	(50)	(49)	(50)
Astrocytoma Benign				1 (2%)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(49)	(50)
Alveolar/Bronchiolar Adenoma			1 (2%)	1 (2%)
Alveolar/Bronchiolar Carcinoma	1 (2%)		1 (2%)	2 (4%)
Carcinoma, Metastatic, Thyroid Gland		1 (2%)	1 (2%)	1 (2%)
Carcinoma, Metastatic, Zymbal's Gland		1 (2%)		
Cholangiocarcinoma, Metastatic, Liver				1 (2%)
Histiocytic Sarcoma, Metastatic, Skin		1 (2%)		
Osteosarcoma, Metastatic, Bone	1 (2%)			
Sarcoma, Metastatic, Heart				1 (2%)
Pleura	(49)	(50)	(49)	(50)
Sarcoma, Metastatic, Heart				1 (2%)
Trachea	(50)	(49)	(49)	(50)
Carcinoma, Metastatic, Thyroid Gland				1 (2%)
SPECIAL SENSES SYSTEM				
Eye	(50)	(49)	(49)	(50)
Carcinoma, Metastatic, Zymbal's Gland				1 (2%)
Zymbal's Gland	(44)	(41)	(39)	(46)
Carcinoma	1 (2%)	2 (5%)		2 (4%)

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
URINARY SYSTEM				
Kidney	(50)	(50)	(49)	(50)
Lipoma		1 (2%)		
Sarcoma, Metastatic, Heart				1 (2%)
Stromal Nephroma				1 (2%)
Cortex, Renal Tubule, Adenoma	1 (2%)	1 (2%)	2 (4%)	2 (4%)
Cortex, Renal Tubule, Adenoma, Multiple			1 (2%)	
Renal Tubule, Carcinoma				1 (2%)
Urinary Bladder	(50)	(49)	(49)	(50)
Transitional Epithelium, Carcinoma				1 (2%)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)		
Leukemia Mononuclear	33 (66%)	31 (62%)	35 (70%)	27 (54%)
Mesothelioma Malignant	2 (4%)	2 (4%)	3 (6%)	4 (8%)

* Number of animals with any tissue examined microscopically

FISCHER 344 RATS MALE	CONTROL	75 PPM	300 PPM	1200 PPM
TUMOR SUMMARY				
Total Animals with Primary Neoplasms (b)	50	50	49	50
Total Primary Neoplasms	154	143	145	162
Total Animals with Benign Neoplasms	50	50	48	49
Total Benign Neoplasms	110	100	98	109
Total Animals with Malignant Neoplasms	35	34	40	40
Total Malignant Neoplasms	44	42	47	53
Total Animals with Metastatic Neoplasms	1	3	2	9
Total Metastatic Neoplasm	1	10	2	18
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain-Benign or Malignant		1		
Total Uncertain Neoplasms		1		

a Number of animals examined microscopically at site and number of animals with lesion
b Primary tumors: all tumors except metastatic tumors

---------- END OF REPORT ----------

FINAL#1/RATS

REASONS FOR REMOVAL: ALL

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS: INCLUDE ALL

NTP
LAB: Battelle Northwest
EXPERIMENT: 90004 TEST: 07
TEST TYPE: CHRONIC
CONT: N01-ES-55392
PATHOLOGIST: RENNE, ROGER
Rats(FISCHER 344)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

CAGES FROM 0000 TO LAST CAGE
ROUTE: RESPIRATORY EXPOSURE WHOLE BODY

REPORT: PEIRPT08
DATE: 11/14/01
TIME: 10:00:52

NTP C#: C90004
CAS: 57018-52-7

FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED. IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.

Adrenal Cortex
Adrenal Medulla
Brain
Clitoral/Preputial Gland
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Ovary
Pituitary Gland
Testes
Thyroid Gland
Urinary Bladder

NTP
LAB: Battelle Northwest
EXPERIMENT: 90004 TEST: 07
TEST TYPE: CHRONIC
CONT: N01-ES-55392
PATHOLOGIST: RENNE, ROGER

STATISTICAL ANALYSIS OF PRIMARY TUMORS
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

CAGES FROM 0000 TO LAST CAGE
ROUTE: RESPIRATORY EXPOSURE WHOLE BODY

REPORT: PEIRPT08
DATE: 11/14/01
TIME: 10:00:52

NTP C#: C90004
CAS: 57018-52-7

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Male Rats

Organ	Morphology
Islets, Pancreatic	Adenoma
Liver	Hepatocellular Adenoma
Skin	Basal Cell Adenoma
	Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma
	Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepitheliom
Testes	Adenoma
All Organs	Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated
	Benign Tumors
	Malignant Tumors
	Malignant and Benign Tumors

Female Rats

Organ	Morphology
Mammary Gland	Carcinoma or Adenoma
Pituitary Gland: Pars Distalis or Unspecified Site	Adenoma
Thyroid Gland: C-Cell	Adenoma
	Carcinoma or Adenoma
Uterus	Polyp Stromal
	Sarcoma Stromal or Polyp Stromal
All Organs	Malignant Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Adrenal Cortex Adenoma								
TUMOR RATES								
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	2/49 (4%)	2/50 (4%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	0/41.77	0/43.38	0/36.82	0/40.72	2/42.54	2/46.42	1/42.02	4/45.37
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	4.7%	4.3%	2.4%	8.8%
TERMINAL (d)	0/27 (0%)	0/29 (0%)	0/16 (0%)	0/22 (0%)	2/33 (6%)	2/34 (6%)	1/28 (4%)	3/36 (8%)
FIRST INCIDENCE	---	---	---	---	730 (T)	730 (T)	730 (T)	684
STATISTICAL TESTS								
LIFE TABLE	(e)	(e)	(e)	(e)	P=0.226	P=0.685N	P=0.558N	P=0.375
POLY 3	(e)	(e)	(e)	(e)	P=0.196	P=0.662N	P=0.504N	P=0.367
POLY 1.5	(e)	(e)	(e)	(e)	P=0.194	P=0.668N	P=0.495N	P=0.362
POLY 6	(e)	(e)	(e)	(e)	P=0.200	P=0.659N	P=0.520N	P=0.372
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.208	P=0.685N	P=0.558N	P=0.369
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	P=0.189	P=0.684N	P=0.492N	P=0.349

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Adrenal Cortex Carcinoma								
TUMOR RATES								
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/49 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/41.77	0/43.38	0/36.82	0/40.72	0/42.54	2/46.74	0/42.02	1/45.19
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	0.0%	4.3%	0.0%	2.2%
TERMINAL (d)	0/27 (0%)	0/29 (0%)	0/16 (0%)	0/22 (0%)	0/33 (0%)	1/34 (3%)	0/28 (0%)	1/36 (3%)
FIRST INCIDENCE	---	---	---	---	---	642	---	730 (T)
STATISTICAL TESTS								
LIFE TABLE	(e)	(e)	(e)	(e)	P=0.648	P=0.260	(e)	P=0.517
POLY 3	(e)	(e)	(e)	(e)	P=0.653	P=0.259	(e)	P=0.512
POLY 1.5	(e)	(e)	(e)	(e)	P=0.648	P=0.254	(e)	P=0.510
POLY 6	(e)	(e)	(e)	(e)	P=0.657	P=0.262	(e)	P=0.513
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.638	P=0.231	(e)	P=0.517
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	P=0.636	P=0.253	(e)	P=0.505

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Adrenal Medulla Pheochromocytoma Benign								
TUMOR RATES								
OVERALL (a)	12/50 (24%)	8/50 (16%)	11/49 (22%)	7/50 (14%)	2/49 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	12/42.68	8/44.59	11/38.15	7/40.75	2/42.65	1/46.42	0/42.02	0/45.19
POLY-3 PERCENT (g)	28.1%	17.9%	28.8%	17.2%	4.7%	2.2%	0.0%	0.0%
TERMINAL (d)	9/27 (33%)	3/29 (10%)	3/16 (19%)	5/22 (23%)	1/33 (3%)	1/34 (3%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	409	621	565	724	702	730 (T)	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.360N	P=0.190N	P=0.250	P=0.281N	P=0.204N	P=0.487N	P=0.278N	P=0.225N
POLY 3	P=0.247N	P=0.189N	P=0.570	P=0.173N	P=0.209N	P=0.471N	P=0.240N	P=0.224N
POLY 1.5	P=0.224N	P=0.204N	P=0.578N	P=0.163N	P=0.211N	P=0.476N	P=0.234N	P=0.226N
POLY 6	P=0.294N	P=0.167N	P=0.506	P=0.195N	P=0.206N	P=0.468N	P=0.251N	P=0.223N
LOGISTIC REGRESSION	P=0.235N	P=0.208N	P=0.508	P=0.190N	P=0.208N	P=0.467N	P=0.249N	P=0.224N
COCH-ARM / FISHERS	P=0.201N	P=0.227N	P=0.522N	P=0.154N	P=0.211N	P=0.492N	P=0.242N	P=0.242N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Adrenal Medulla Pheochromocytoma Malignant								
TUMOR RATES								
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/49 (0%)	2/50 (4%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/42.04	0/43.38	0/36.82	2/40.96	0/42.54	0/46.42	0/42.02	1/45.19
POLY-3 PERCENT (g)	4.8%	0.0%	0.0%	4.9%	0.0%	0.0%	0.0%	2.2%
TERMINAL (d)	1/27 (4%)	0/29 (0%)	0/16 (0%)	1/22 (5%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	1/36 (3%)
FIRST INCIDENCE	656	---	---	663	---	---	---	730 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.308	P=0.220N	P=0.324N	P=0.647	P=0.248	(e)	(e)	P=0.517
POLY 3	P=0.337	P=0.230N	P=0.267N	P=0.685	P=0.231	(e)	(e)	P=0.512
POLY 1.5	P=0.341	P=0.232N	P=0.254N	P=0.690	P=0.231	(e)	(e)	P=0.510
POLY 6	P=0.329	P=0.228N	P=0.289N	P=0.674	P=0.231	(e)	(e)	P=0.513
LOGISTIC REGRESSION	P=0.338	P=0.233N	P=0.265N	P=0.688	(e)	(e)	(e)	P=0.517
COCH-ARM / FISHERS	P=0.347	P=0.247N	P=0.253N	P=0.691N	P=0.229	(e)	(e)	P=0.505

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Islets, Pancreatic Carcinoma or Adenoma								
TUMOR RATES								
OVERALL (a)	4/50 (8%)	4/50 (8%)	6/49 (12%)	1/50 (2%)	1/49 (2%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	4/41.84	4/43.39	6/37.75	1/40.72	1/42.54	1/46.42	1/42.02	2/45.19
POLY-3 PERCENT (g)	9.6%	9.2%	15.9%	2.5%	2.4%	2.2%	2.4%	4.4%
TERMINAL (d)	3/27 (11%)	3/29 (10%)	2/16 (13%)	1/22 (5%)	1/33 (3%)	1/34 (3%)	1/28 (4%)	2/36 (6%)
FIRST INCIDENCE	712	726	642	729 (T)	730 (T)	730 (T)	730 (T)	730 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.181N	P=0.604N	P=0.156	P=0.247N	P=0.406	P=0.755N	P=0.725	P=0.530
POLY 3	P=0.124N	P=0.624N	P=0.304	P=0.186N	P=0.377	P=0.741N	P=0.758	P=0.521
POLY 1.5	P=0.118N	P=0.629N	P=0.330	P=0.182N	P=0.376	P=0.745N	P=0.757N	P=0.518
POLY 6	P=0.137N	P=0.618N	P=0.268	P=0.196N	P=0.379	P=0.739N	P=0.748	P=0.523
LOGISTIC REGRESSION	P=0.138N	P=0.599N	P=0.246	P=0.224N	P=0.406	P=0.755N	P=0.725	P=0.530
COCH-ARM / FISHERS	P=0.113N	P=0.643N	P=0.357	P=0.181N	P=0.372	P=0.747N	P=0.747N	P=0.508

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Kidney: Renal Tubule Adenoma								
TUMOR RATES								
OVERALL (a)	1/50 (2%)	1/50 (2%)	3/49 (6%)	2/50 (4%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/42.04	1/43.38	3/37.04	2/40.89	0/42.54	0/46.42	0/42.02	1/45.19
POLY-3 PERCENT (g)	2.4%	2.3%	8.1%	4.9%	0.0%	0.0%	0.0%	2.2%
TERMINAL (d)	0/27 (0%)	1/29 (3%)	1/16 (6%)	1/22 (5%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	1/36 (3%)
FIRST INCIDENCE	655	729 (T)	681	683	---	---	---	730 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.385	P=0.747N	P=0.182	P=0.459	P=0.248	(e)	(e)	P=0.517
POLY 3	P=0.423	P=0.754N	P=0.260	P=0.490	P=0.231	(e)	(e)	P=0.512
POLY 1.5	P=0.435	P=0.756N	P=0.279	P=0.496	P=0.231	(e)	(e)	P=0.510
POLY 6	P=0.402	P=0.753N	P=0.233	P=0.478	P=0.231	(e)	(e)	P=0.513
LOGISTIC REGRESSION	P=0.423	P=0.759N	P=0.245	P=0.495	(e)	(e)	(e)	P=0.517
COCH-ARM / FISHERS	P=0.447	P=0.753N	P=0.301	P=0.500	P=0.229	(e)	(e)	P=0.505

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Kidney: Renal Tubule Carcinoma or Adenoma								
TUMOR RATES								
OVERALL (a)	1/50 (2%)	1/50 (2%)	3/49 (6%)	3/50 (6%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/42.04	1/43.38	3/37.04	3/40.89	0/42.54	0/46.42	0/42.02	1/45.19
POLY-3 PERCENT (g)	2.4%	2.3%	8.1%	7.3%	0.0%	0.0%	0.0%	2.2%
TERMINAL (d)	0/27 (0%)	1/29 (3%)	1/16 (6%)	2/22 (9%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	1/36 (3%)
FIRST INCIDENCE	655	729 (T)	681	683	---	---	---	730 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.183	P=0.747N	P=0.182	P=0.259	P=0.248	(e)	(e)	P=0.517
POLY 3	P=0.214	P=0.754N	P=0.260	P=0.295	P=0.231	(e)	(e)	P=0.512
POLY 1.5	P=0.223	P=0.756N	P=0.279	P=0.301	P=0.231	(e)	(e)	P=0.510
POLY 6	P=0.198	P=0.753N	P=0.233	P=0.282	P=0.231	(e)	(e)	P=0.513
LOGISTIC REGRESSION	P=0.209	P=0.759N	P=0.245	P=0.293	(e)	(e)	(e)	P=0.517
COCH-ARM / FISHERS	P=0.232	P=0.753N	P=0.301	P=0.309	P=0.229	(e)	(e)	P=0.505

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Liver Hepatocellular Adenoma								
TUMOR RATES								
OVERALL (a)	3/50 (6%)	0/50 (0%)	2/49 (4%)	6/50 (12%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	3/41.84	0/43.38	2/37.00	6/41.90	1/42.54	0/46.42	0/42.02	2/45.21
POLY-3 PERCENT (g)	7.2%	0.0%	5.4%	14.3%	2.4%	0.0%	0.0%	4.4%
TERMINAL (d)	2/27 (7%)	0/29 (0%)	1/16 (6%)	2/22 (9%)	1/33 (3%)	0/34 (0%)	0/28 (0%)	1/36 (3%)
FIRST INCIDENCE	712	---	684	537	730 (T)	---	---	726
STATISTICAL TESTS								
LIFE TABLE	P=0.017 *	P=0.113N	P=0.654	P=0.183	P=0.204	P=0.494N	P=0.533N	P=0.533
POLY 3	P=0.022 *	P=0.112N	P=0.556N	P=0.241	P=0.176	P=0.483N	P=0.502N	P=0.521
POLY 1.5	P=0.023 *	P=0.114N	P=0.533N	P=0.243	P=0.176	P=0.486N	P=0.497N	P=0.518
POLY 6	P=0.021 *	P=0.109N	P=0.592N	P=0.233	P=0.177	P=0.481N	P=0.512N	P=0.524
LOGISTIC REGRESSION	P=0.023 *	P=0.106N	P=0.644N	P=0.235	P=0.197	(e)	(e)	P=0.532
COCH-ARM / FISHERS	P=0.026 *	P=0.121N	P=0.510N	P=0.243	P=0.177	P=0.495N	P=0.495N	P=0.508

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Lung Alveolar/Bronchiolar Carcinoma								
TUMOR RATES								
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/49 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/41.77	0/43.38	1/36.95	2/41.10	0/42.73	0/46.42	0/42.02	0/45.19
POLY-3 PERCENT (g)	2.4%	0.0%	2.7%	4.9%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	1/27 (4%)	0/29 (0%)	0/16 (0%)	0/22 (0%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	---	697	662	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.203	P=0.486N	P=0.656	P=0.457	(e)	(e)	(e)	(e)
POLY 3	P=0.229	P=0.492N	P=0.733	P=0.494	(e)	(e)	(e)	(e)
POLY 1.5	P=0.234	P=0.495N	P=0.745	P=0.498	(e)	(e)	(e)	(e)
POLY 6	P=0.220	P=0.490N	P=0.714	P=0.486	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.231	(e)	P=0.701	P=0.491	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.239	P=0.500N	P=0.747	P=0.500	(e)	(e)	(e)	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Lung Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma								
TUMOR RATES								
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/49 (2%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/41.77	0/43.38	1/36.95	3/41.10	0/42.73	0/46.42	0/42.02	0/45.19
POLY-3 PERCENT (g)	2.4%	0.0%	2.7%	7.3%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	1/27 (4%)	0/29 (0%)	0/16 (0%)	1/22 (5%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	---	697	662	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.062	P=0.486N	P=0.656	P=0.258	(e)	(e)	(e)	(e)
POLY 3	P=0.075	P=0.492N	P=0.733	P=0.299	(e)	(e)	(e)	(e)
POLY 1.5	P=0.078	P=0.495N	P=0.745	P=0.303	(e)	(e)	(e)	(e)
POLY 6	P=0.071	P=0.490N	P=0.714	P=0.290	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.074	(e)	P=0.701	P=0.287	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.081	P=0.500N	P=0.747	P=0.309	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Lung								
Squamous Cell Carcinoma								
TUMOR RATES								
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/41.77	0/43.38	0/36.82	0/40.72	0/42.73	0/46.42	2/43.15	0/45.19
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	4.6%	0.0%
TERMINAL (d)	0/27 (0%)	0/29 (0%)	0/16 (0%)	0/22 (0%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---	---	---	471	---
STATISTICAL TESTS								
LIFE TABLE	(e)	(e)	(e)	(e)	P=0.647N	(e)	P=0.246	(e)
POLY 3	(e)	(e)	(e)	(e)	P=0.648N	(e)	P=0.239	(e)
POLY 1.5	(e)	(e)	(e)	(e)	P=0.649N	(e)	P=0.242	(e)
POLY 6	(e)	(e)	(e)	(e)	P=0.648N	(e)	P=0.233	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.708N	(e)	P=0.141	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	P=0.652N	(e)	P=0.247	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Mammary Gland								
Adenoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/41.77	0/43.38	0/36.82	0/40.72	0/42.73	2/46.42	0/42.02	0/45.19
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	0.0%	4.3%	0.0%	0.0%
TERMINAL (d)	0/27 (0%)	0/29 (0%)	0/16 (0%)	0/22 (0%)	0/33 (0%)	2/34 (6%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---	---	730 (T)	---	---
STATISTICAL TESTS								
LIFE TABLE	(e)	(e)	(e)	(e)	P=0.373N	P=0.245	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)	P=0.366N	P=0.256	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	P=0.373N	P=0.251	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	P=0.358N	P=0.259	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.245	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	P=0.390N	P=0.247	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Mammary Gland Carcinoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	1/50 (2%)	5/50 (10%)	4/50 (8%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/41.77	2/43.69	2/37.46	1/40.84	5/42.73	4/46.87	1/42.02	1/45.19
POLY-3 PERCENT (g)	0.0%	4.6%	5.3%	2.5%	11.7%	8.5%	2.4%	2.2%
TERMINAL (d)	0/27 (0%)	1/29 (3%)	0/16 (0%)	0/22 (0%)	5/33 (15%)	2/34 (6%)	1/28 (4%)	1/36 (3%)
FIRST INCIDENCE	---	642	593	698	730 (T)	656	730 (T)	730 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.627	P=0.256	P=0.191	P=0.465	P=0.077N	P=0.473N	P=0.142N	P=0.083N
POLY 3	P=0.658	P=0.247	P=0.213	P=0.495	P=0.083N	P=0.442N	P=0.104N	P=0.089N
POLY 1.5	P=0.661N	P=0.244	P=0.223	P=0.498	P=0.085N	P=0.458N	P=0.100N	P=0.092N
POLY 6	P=0.643	P=0.251	P=0.199	P=0.490	P=0.081N	P=0.429N	P=0.114N	P=0.086N
LOGISTIC REGRESSION	P=0.659N	P=0.238	P=0.246	P=0.494	P=0.083N	P=0.446N	P=0.142N	P=0.083N
COCH-ARM / FISHERS	P=0.658N	P=0.247	P=0.247	P=0.500	P=0.089N	P=0.500N	P=0.102N	P=0.102N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Mammary Gland Carcinoma or Adenoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	1/50 (2%)	5/50 (10%)	6/50 (12%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/41.77	2/43.69	2/37.46	1/40.84	5/42.73	6/46.87	1/42.02	1/45.19
POLY-3 PERCENT (g)	0.0%	4.6%	5.3%	2.5%	11.7%	12.8%	2.4%	2.2%
TERMINAL (d)	0/27 (0%)	1/29 (3%)	0/16 (0%)	0/22 (0%)	5/33 (15%)	4/34 (12%)	1/28 (4%)	1/36 (3%)
FIRST INCIDENCE	---	642	593	698	730 (T)	656	730 (T)	730 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.627	P=0.256	P=0.191	P=0.465	P=0.044N*	P=0.529	P=0.142N	P=0.083N
POLY 3	P=0.658	P=0.247	P=0.213	P=0.495	P=0.045N*	P=0.565	P=0.104N	P=0.089N
POLY 1.5	P=0.661N	P=0.244	P=0.223	P=0.498	P=0.046N*	P=0.546	P=0.100N	P=0.092N
POLY 6	P=0.643	P=0.251	P=0.199	P=0.490	P=0.042N*	P=0.579	P=0.114N	P=0.086N
LOGISTIC REGRESSION	P=0.659N	P=0.238	P=0.246	P=0.494	P=0.047N*	P=0.565	P=0.142N	P=0.083N
COCH-ARM / FISHERS	P=0.658N	P=0.247	P=0.247	P=0.500	P=0.052N	P=0.500	P=0.102N	P=0.102N

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Mammary Gland Fibroadenoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	3/50 (6%)	3/50 (6%)	25/50 (50%)	29/50 (58%)	21/50 (42%)	29/50 (58%)
POLY-3 RATE (b)	2/41.77	2/43.69	3/37.52	3/41.24	25/43.37	29/47.72	21/43.87	29/46.02
POLY-3 PERCENT (g)	4.8%	4.6%	8.0%	7.3%	57.7%	60.8%	47.9%	63.0%
TERMINAL (d)	2/27 (7%)	1/29 (3%)	1/16 (6%)	1/22 (5%)	23/33 (70%)	21/34 (62%)	12/28 (43%)	23/36 (64%)
FIRST INCIDENCE	729 (T)	642	621	656	558	642	610	642
STATISTICAL TESTS								
LIFE TABLE	P=0.364	P=0.668N	P=0.320	P=0.439	P=0.496	P=0.357	P=0.528N	P=0.446
POLY 3	P=0.413	P=0.678N	P=0.451	P=0.494	P=0.321	P=0.464	P=0.236N	P=0.378
POLY 1.5	P=0.422	P=0.683N	P=0.471	P=0.498	P=0.312	P=0.402	P=0.233N	P=0.347
POLY 6	P=0.397	P=0.671N	P=0.421	P=0.485	P=0.334	P=0.526	P=0.249N	P=0.414
LOGISTIC REGRESSION	P=0.421	P=0.680N	P=0.442	P=0.483	P=0.348	P=0.473	P=0.343N	P=0.396
COCH-ARM / FISHERS	P=0.429	P=0.691N	P=0.500	P=0.500	P=0.290	P=0.274	P=0.274N	P=0.274

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Mammary Gland Fibroma, Fibroadenoma or Adenoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	3/50 (6%)	3/50 (6%)	25/50 (50%)	30/50 (60%)	21/50 (42%)	29/50 (58%)
POLY-3 RATE (b)	2/41.77	2/43.69	3/37.52	3/41.24	25/43.37	30/47.72	21/43.87	29/46.02
POLY-3 PERCENT (g)	4.8%	4.6%	8.0%	7.3%	57.7%	62.9%	47.9%	63.0%
TERMINAL (d)	2/27 (7%)	1/29 (3%)	1/16 (6%)	1/22 (5%)	23/33 (70%)	22/34 (65%)	12/28 (43%)	23/36 (64%)
FIRST INCIDENCE	729 (T)	642	621	656	558	642	610	642
STATISTICAL TESTS								
LIFE TABLE	P=0.364	P=0.668N	P=0.320	P=0.439	P=0.532	P=0.285	P=0.528N	P=0.446
POLY 3	P=0.413	P=0.678N	P=0.451	P=0.494	P=0.360	P=0.382	P=0.236N	P=0.378
POLY 1.5	P=0.422	P=0.683N	P=0.471	P=0.498	P=0.349	P=0.325	P=0.233N	P=0.347
POLY 6	P=0.397	P=0.671N	P=0.421	P=0.485	P=0.376	P=0.442	P=0.249N	P=0.414
LOGISTIC REGRESSION	P=0.421	P=0.680N	P=0.442	P=0.483	P=0.386	P=0.394	P=0.343N	P=0.396
COCH-ARM / FISHERS	P=0.429	P=0.691N	P=0.500	P=0.500	P=0.323	P=0.211	P=0.274N	P=0.274

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	5/50 (10%)	4/50 (8%)	27/50 (54%)	32/50 (64%)	21/50 (42%)	29/50 (58%)
POLY-3 RATE (b)	2/41.77	3/43.69	5/38.16	4/41.36	27/43.37	32/47.90	21/43.87	29/46.02
POLY-3 PERCENT (g)	4.8%	6.9%	13.1%	9.7%	62.3%	66.8%	47.9%	63.0%
TERMINAL (d)	2/27 (7%)	2/29 (7%)	1/16 (6%)	1/22 (5%)	25/33 (76%)	23/34 (68%)	12/28 (43%)	23/36 (64%)
FIRST INCIDENCE	729 (T)	642	593	656	558	642	610	642
STATISTICAL TESTS								
LIFE TABLE	P=0.301	P=0.533	P=0.104	P=0.278	P=0.405N	P=0.289	P=0.385N	P=0.547N
POLY 3	P=0.354	P=0.521	P=0.179	P=0.332	P=0.540	P=0.405	P=0.120N	P=0.559
POLY 1.5	P=0.363	P=0.514	P=0.193	P=0.336	P=0.524	P=0.337	P=0.121N	P=0.518
POLY 6	P=0.336	P=0.529	P=0.159	P=0.323	P=0.559	P=0.482	P=0.125N	P=0.580N
LOGISTIC REGRESSION	P=0.365	P=0.523	P=0.190	P=0.319	P=0.548N	P=0.411	P=0.206N	P=0.579
COCH-ARM / FISHERS	P=0.372	P=0.500	P=0.218	P=0.339	P=0.484	P=0.208	P=0.158N	P=0.420

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma								
TUMOR RATES								
OVERALL (a)	35/50 (70%)	27/50 (54%)	26/49 (53%)	32/50 (64%)	30/49 (61%)	36/50 (72%)	32/50 (64%)	22/49 (45%)
POLY-3 RATE (b)	35/46.77	27/46.42	26/42.14	32/45.38	30/44.48	36/49.68	32/45.65	22/46.71
POLY-3 PERCENT (g)	74.8%	58.2%	61.7%	70.5%	67.4%	72.5%	70.1%	47.1%
TERMINAL (d)	21/27 (78%)	16/29 (55%)	9/16 (56%)	15/22 (68%)	23/33 (70%)	21/34 (62%)	20/28 (71%)	15/36 (42%)
FIRST INCIDENCE	296	509	431	518	537	410	528	586
STATISTICAL TESTS								
LIFE TABLE	P=0.193	P=0.070N	P=0.406	P=0.456	P=0.008N**	P=0.294	P=0.176	P=0.051N
POLY 3	P=0.382	P=0.060N	P=0.121N	P=0.404N	P=0.003N**	P=0.379	P=0.482	P=0.036N*
POLY 1.5	P=0.401	P=0.064N	P=0.089N	P=0.378N	P=0.004N**	P=0.312	P=0.506	P=0.043N*
POLY 6	P=0.357	P=0.060N	P=0.182N	P=0.444N	P=0.003N**	P=0.450	P=0.438	P=0.031N*
LOGISTIC REGRESSION	P=0.412	P=0.063N	P=0.091N	P=0.345N	P=0.005N**	P=0.256	P=0.424	P=0.043N*
COCH-ARM / FISHERS	P=0.444	P=0.074N	P=0.063N	P=0.335N	P=0.008N**	P=0.178	P=0.469	P=0.078N

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin								
Basal Cell Adenoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/41.77	1/43.38	0/36.82	3/40.84	0/42.73	0/46.42	0/42.02	0/45.19
POLY-3 PERCENT (g)	0.0%	2.3%	0.0%	7.4%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	0/27 (0%)	1/29 (3%)	0/16 (0%)	2/22 (9%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	---	698	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.029 *	P=0.514	(e)	P=0.090	(e)	(e)	(e)	(e)
POLY 3	P=0.038 *	P=0.508	(e)	P=0.114	(e)	(e)	(e)	(e)
POLY 1.5	P=0.039 *	P=0.505	(e)	P=0.117	(e)	(e)	(e)	(e)
POLY 6	P=0.037 *	P=0.510	(e)	P=0.108	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.032 *	P=0.514	(e)	P=0.100	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.041 *	P=0.500	(e)	P=0.121	(e)	(e)	(e)	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin								
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	4/50 (8%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/41.77	1/43.38	0/36.82	4/40.86	0/42.73	0/46.42	0/42.02	0/45.19
POLY-3 PERCENT (g)	0.0%	2.3%	0.0%	9.8%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	0/27 (0%)	1/29 (3%)	0/16 (0%)	2/22 (9%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	---	698	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.007 **	P=0.514	(e)	P=0.045 *	(e)	(e)	(e)	(e)
POLY 3	P=0.009 **	P=0.508	(e)	P=0.057	(e)	(e)	(e)	(e)
POLY 1.5	P=0.009 **	P=0.505	(e)	P=0.059	(e)	(e)	(e)	(e)
POLY 6	P=0.008 **	P=0.510	(e)	P=0.053	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.007 **	P=0.514	(e)	P=0.047 *	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.010 *	P=0.500	(e)	P=0.059	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepitheliom								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	5/50 (10%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/42.12	1/43.38	1/36.88	5/41.10	0/42.73	0/46.42	0/42.02	1/45.42
POLY-3 PERCENT (g)	4.8%	2.3%	2.7%	12.2%	0.0%	0.0%	0.0%	2.2%
TERMINAL (d)	1/27 (4%)	1/29 (3%)	0/16 (0%)	2/22 (9%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	631	729 (T)	716	666	---	---	---	669
STATISTICAL TESTS								
LIFE TABLE	P=0.032 *	P=0.481N	P=0.635N	P=0.168	P=0.241	(e)	(e)	P=0.514
POLY 3	P=0.040 *	P=0.490N	P=0.546N	P=0.205	P=0.231	(e)	(e)	P=0.512
POLY 1.5	P=0.042 *	P=0.492N	P=0.527N	P=0.211	P=0.231	(e)	(e)	P=0.509
POLY 6	P=0.037 *	P=0.487N	P=0.577N	P=0.192	P=0.232	(e)	(e)	P=0.515
LOGISTIC REGRESSION	P=0.038 *	P=0.491N	P=0.548N	P=0.200	P=0.222	(e)	(e)	P=0.492
COCH-ARM / FISHERS	P=0.045 *	P=0.500N	P=0.500N	P=0.218	P=0.228	(e)	(e)	P=0.500

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin Fibroma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	2/50 (4%)	4/50 (8%)	2/50 (4%)	4/50 (8%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/41.84	4/44.26	2/36.95	4/40.99	1/42.95	0/46.42	0/42.02	0/45.19
POLY-3 PERCENT (g)	4.8%	9.0%	5.4%	9.8%	2.3%	0.0%	0.0%	0.0%
TERMINAL (d)	1/27 (4%)	2/29 (7%)	1/16 (6%)	3/22 (14%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	712	513	697	655	670	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.290	P=0.369	P=0.512	P=0.259	P=0.541N	P=0.486N	P=0.521N	P=0.490N
POLY 3	P=0.359	P=0.363	P=0.649	P=0.327	P=0.553N	P=0.485N	P=0.504N	P=0.490N
POLY 1.5	P=0.367	P=0.354	P=0.668	P=0.333	P=0.553N	P=0.488N	P=0.500N	P=0.492N
POLY 6	P=0.341	P=0.374	P=0.618	P=0.313	P=0.551N	P=0.483N	P=0.514N	P=0.489N
LOGISTIC REGRESSION	P=0.355	P=0.334	P=0.578	P=0.296	P=0.552N	P=0.518N	P=0.501N	P=0.508N
COCH-ARM / FISHERS	P=0.372	P=0.339	P=0.691N	P=0.339	P=0.547N	P=0.500N	P=0.500N	P=0.500N

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	3/50 (6%)	4/50 (8%)	2/50 (4%)	5/50 (10%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/41.84	4/44.26	2/36.95	5/41.32	3/43.12	0/46.42	0/42.02	1/45.37
POLY-3 PERCENT (g)	7.2%	9.0%	5.4%	12.1%	7.0%	0.0%	0.0%	2.2%
TERMINAL (d)	2/27 (7%)	2/29 (7%)	1/16 (6%)	3/22 (14%)	1/33 (3%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	712	513	697	639	670	---	---	684
STATISTICAL TESTS								
LIFE TABLE	P=0.218	P=0.534	P=0.646	P=0.270	P=0.513N	P=0.117N	P=0.148N	P=0.290N
POLY 3	P=0.283	P=0.531	P=0.557N	P=0.348	P=0.540N	P=0.106N	P=0.123N	P=0.287N
POLY 1.5	P=0.290	P=0.520	P=0.533N	P=0.354	P=0.540N	P=0.109N	P=0.119N	P=0.291N
POLY 6	P=0.269	P=0.544	P=0.593N	P=0.336	P=0.535N	P=0.105N	P=0.132N	P=0.285N
LOGISTIC REGRESSION	P=0.279	P=0.505	P=0.655N	P=0.325	P=0.531N	P=0.115N	P=0.121N	P=0.299N
COCH-ARM / FISHERS	P=0.294	P=0.500	P=0.500N	P=0.357	P=0.532N	P=0.121N	P=0.121N	P=0.309N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/41.77	0/43.38	0/36.82	1/41.04	2/42.89	0/46.42	0/42.02	1/45.37
POLY-3 PERCENT (g)	2.4%	0.0%	0.0%	2.4%	4.7%	0.0%	0.0%	2.2%
TERMINAL (d)	1/27 (4%)	0/29 (0%)	0/16 (0%)	0/22 (0%)	1/33 (3%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	---	---	639	687	---	---	684
STATISTICAL TESTS								
LIFE TABLE	P=0.491	P=0.486N	P=0.604N	P=0.729	P=0.694N	P=0.234N	P=0.270N	P=0.481N
POLY 3	P=0.514	P=0.492N	P=0.525N	P=0.757	P=0.695	P=0.220N	P=0.242N	P=0.480N
POLY 1.5	P=0.517	P=0.495N	P=0.515N	P=0.759	P=0.695	P=0.224N	P=0.236N	P=0.485N
POLY 6	P=0.506	P=0.490N	P=0.542N	P=0.752	P=0.696	P=0.218N	P=0.252N	P=0.477N
LOGISTIC REGRESSION	P=0.519	(e)	(e)	P=0.761	P=0.702	P=0.223N	P=0.243N	P=0.490N
COCH-ARM / FISHERS	P=0.522	P=0.500N	P=0.500N	P=0.753N	P=0.700	P=0.247N	P=0.247N	P=0.500N

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin Lipoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/41.77	2/43.47	1/36.82	0/40.72	0/42.73	0/46.42	1/42.25	0/45.19
POLY-3 PERCENT (g)	2.4%	4.6%	2.7%	0.0%	0.0%	0.0%	2.4%	0.0%
TERMINAL (d)	1/27 (4%)	1/29 (3%)	1/16 (6%)	0/22 (0%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	705	729 (T)	---	---	---	670	---
STATISTICAL TESTS								
LIFE TABLE	P=0.293N	P=0.527	P=0.641	P=0.541N	P=0.764N	(e)	P=0.479	(e)
POLY 3	P=0.241N	P=0.514	P=0.732	P=0.505N	P=0.770N	(e)	P=0.498	(e)
POLY 1.5	P=0.239N	P=0.509	P=0.744	P=0.502N	P=0.770N	(e)	P=0.502	(e)
POLY 6	P=0.247N	P=0.519	P=0.712	P=0.512N	P=0.769N	(e)	P=0.490	(e)
LOGISTIC REGRESSION	P=0.274N	P=0.525	P=0.641	(e)	P=0.777N	(e)	P=0.499	(e)
COCH-ARM / FISHERS	P=0.238N	P=0.500	P=0.753N	P=0.500N	P=0.772N	(e)	P=0.500	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/42.12	0/43.38	1/36.88	1/40.95	0/42.73	0/46.42	0/42.02	1/45.42
POLY-3 PERCENT (g)	4.8%	0.0%	2.7%	2.4%	0.0%	0.0%	0.0%	2.2%
TERMINAL (d)	1/27 (4%)	0/29 (0%)	0/16 (0%)	0/22 (0%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	631	---	716	666	---	---	---	669
STATISTICAL TESTS								
LIFE TABLE	P=0.674	P=0.229N	P=0.635N	P=0.537N	P=0.241	(e)	(e)	P=0.514
POLY 3	P=0.662N	P=0.230N	P=0.546N	P=0.510N	P=0.231	(e)	(e)	P=0.512
POLY 1.5	P=0.658N	P=0.232N	P=0.527N	P=0.504N	P=0.231	(e)	(e)	P=0.509
POLY 6	P=0.670N	P=0.229N	P=0.577N	P=0.522N	P=0.232	(e)	(e)	P=0.515
LOGISTIC REGRESSION	P=0.658N	P=0.238N	P=0.548N	P=0.500N	P=0.222	(e)	(e)	P=0.492
COCH-ARM / FISHERS	P=0.654N	P=0.247N	P=0.500N	P=0.500N	P=0.228	(e)	(e)	P=0.500

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin								
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/42.12	0/43.38	1/36.88	1/40.95	0/42.73	0/46.42	0/42.02	1/45.42
POLY-3 PERCENT (g)	4.8%	0.0%	2.7%	2.4%	0.0%	0.0%	0.0%	2.2%
TERMINAL (d)	1/27 (4%)	0/29 (0%)	0/16 (0%)	0/22 (0%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	631	---	716	666	---	---	---	669
STATISTICAL TESTS								
LIFE TABLE	P=0.674	P=0.229N	P=0.635N	P=0.537N	P=0.241	(e)	(e)	P=0.514
POLY 3	P=0.662N	P=0.230N	P=0.546N	P=0.510N	P=0.231	(e)	(e)	P=0.512
POLY 1.5	P=0.658N	P=0.232N	P=0.527N	P=0.504N	P=0.231	(e)	(e)	P=0.509
POLY 6	P=0.670N	P=0.229N	P=0.577N	P=0.522N	P=0.232	(e)	(e)	P=0.515
LOGISTIC REGRESSION	P=0.658N	P=0.238N	P=0.548N	P=0.500N	P=0.222	(e)	(e)	P=0.492
COCH-ARM / FISHERS	P=0.654N	P=0.247N	P=0.500N	P=0.500N	P=0.228	(e)	(e)	P=0.500

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Testes								
Adenoma								
TUMOR RATES								
OVERALL (a)	41/50 (82%)	45/50 (90%)	40/49 (82%)	42/50 (84%)				
POLY-3 RATE (b)	41/45.93	45/48.37	40/45.72	42/46.78				
POLY-3 PERCENT (g)	89.3%	93.0%	87.5%	89.8%				
TERMINAL (d)	25/27 (93%)	28/29 (97%)	16/16 (100%)	22/22 (100%)				
FIRST INCIDENCE	458	464	431	509				
STATISTICAL TESTS								
LIFE TABLE	P=0.187	P=0.498	P=0.020 *	P=0.158				
POLY 3	P=0.529N	P=0.377	P=0.527N	P=0.616				
POLY 1.5	P=0.510N	P=0.298	P=0.532N	P=0.576				
POLY 6	P=0.615N	P=0.474	P=0.580N	P=0.617				
LOGISTIC REGRESSION	P=0.530N	P=0.286	P=0.467	P=0.504				
COCH-ARM / FISHERS	P=0.499N	P=0.194	P=0.584N	P=0.500				

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Thyroid Gland: C-Cell Adenoma								
TUMOR RATES								
OVERALL (a)	3/50 (6%)	4/50 (8%)	3/49 (6%)	5/50 (10%)	8/49 (16%)	2/50 (4%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	3/41.90	4/43.50	3/37.30	5/40.74	8/43.38	2/46.43	3/42.48	4/45.42
POLY-3 PERCENT (g)	7.2%	9.2%	8.0%	12.3%	18.4%	4.3%	7.1%	8.8%
TERMINAL (d)	1/27 (4%)	3/29 (10%)	1/16 (6%)	4/22 (18%)	5/33 (15%)	1/34 (3%)	2/28 (7%)	3/36 (8%)
FIRST INCIDENCE	712	697	634	724	537	726	593	669
STATISTICAL TESTS								
LIFE TABLE	P=0.224	P=0.536	P=0.455	P=0.257	P=0.367N	P=0.046N*	P=0.156N	P=0.148N
POLY 3	P=0.299	P=0.520	P=0.608	P=0.340	P=0.411N	P=0.034N*	P=0.103N	P=0.154N
POLY 1.5	P=0.310	P=0.514	P=0.631	P=0.350	P=0.412N	P=0.036N*	P=0.095N	P=0.156N
POLY 6	P=0.276	P=0.527	P=0.572	P=0.319	P=0.404N	P=0.034N*	P=0.119N	P=0.153N
LOGISTIC REGRESSION	P=0.260	P=0.537	P=0.571	P=0.275	P=0.404N	P=0.039N*	P=0.096N	P=0.156N
COCH-ARM / FISHERS	P=0.320	P=0.500	P=0.651	P=0.357	P=0.410N	P=0.043N*	P=0.094N	P=0.168N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Thyroid Gland: C-Cell Carcinoma								
TUMOR RATES								
OVERALL (a)	1/50 (2%)	1/50 (2%)	3/49 (6%)	3/50 (6%)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/42.00	1/43.76	3/38.07	3/40.90	2/43.01	0/46.42	0/42.02	0/45.19
POLY-3 PERCENT (g)	2.4%	2.3%	7.9%	7.3%	4.7%	0.0%	0.0%	0.0%
TERMINAL (d)	0/27 (0%)	0/29 (0%)	0/16 (0%)	2/22 (9%)	1/33 (3%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	668	621	509	681	593	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.200	P=0.751N	P=0.241	P=0.254	P=0.303N	P=0.222N	P=0.258N	P=0.225N
POLY 3	P=0.213	P=0.752N	P=0.270	P=0.295	P=0.310N	P=0.220N	P=0.242N	P=0.226N
POLY 1.5	P=0.222	P=0.754N	P=0.284	P=0.301	P=0.311N	P=0.223N	P=0.235N	P=0.227N
POLY 6	P=0.196	P=0.749N	P=0.247	P=0.283	P=0.307N	P=0.220N	P=0.254N	P=0.226N
LOGISTIC REGRESSION	P=0.238	P=0.745	P=0.324	P=0.290	P=0.311N	P=0.253N	P=0.236N	P=0.243N
COCH-ARM / FISHERS	P=0.232	P=0.753N	P=0.301	P=0.309	P=0.306N	P=0.242N	P=0.242N	P=0.242N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Thyroid Gland: C-Cell Carcinoma or Adenoma								
TUMOR RATES								
OVERALL (a)	4/50 (8%)	5/50 (10%)	6/49 (12%)	7/50 (14%)	9/49 (18%)	2/50 (4%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	4/42.14	5/43.88	6/38.54	7/40.92	9/43.85	2/46.43	3/42.48	4/45.42
POLY-3 PERCENT (g)	9.5%	11.4%	15.6%	17.1%	20.5%	4.3%	7.1%	8.8%
TERMINAL (d)	1/27 (4%)	3/29 (10%)	1/16 (6%)	5/22 (23%)	5/33 (15%)	1/34 (3%)	2/28 (7%)	3/36 (8%)
FIRST INCIDENCE	668	621	509	681	537	726	593	669
STATISTICAL TESTS								
LIFE TABLE	P=0.168	P=0.537	P=0.195	P=0.175	P=0.300N	P=0.026N*	P=0.103N	P=0.098N
POLY 3	P=0.216	P=0.526	P=0.313	P=0.241	P=0.335N	P=0.019N*	P=0.065N	P=0.101N
POLY 1.5	P=0.232	P=0.517	P=0.335	P=0.253	P=0.337N	P=0.020N*	P=0.058N	P=0.101N
POLY 6	P=0.189	P=0.534	P=0.277	P=0.219	P=0.329N	P=0.019N*	P=0.079N	P=0.102N
LOGISTIC REGRESSION	P=0.230	P=0.523	P=0.350	P=0.205	P=0.333N	P=0.024N*	P=0.057N	P=0.105N
COCH-ARM / FISHERS	P=0.247	P=0.500	P=0.357	P=0.262	P=0.335N	P=0.023N*	P=0.056N	P=0.109N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Thyroid Gland: Follicular Cell Carcinoma or Adenoma								
TUMOR RATES								
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/49 (0%)	2/50 (4%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/42.04	1/43.47	0/36.82	2/41.38	0/42.54	1/46.42	0/42.02	0/45.19
POLY-3 PERCENT (g)	2.4%	2.3%	0.0%	4.8%	0.0%	2.2%	0.0%	0.0%
TERMINAL (d)	0/27 (0%)	0/29 (0%)	0/16 (0%)	0/22 (0%)	0/33 (0%)	1/34 (3%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	656	705	---	582	---	730 (T)	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.289	P=0.738N	P=0.545N	P=0.481	P=0.589N	P=0.506	(e)	(e)
POLY 3	P=0.316	P=0.753N	P=0.526N	P=0.494	P=0.591N	P=0.517	(e)	(e)
POLY 1.5	P=0.318	P=0.755N	P=0.515N	P=0.498	P=0.596N	P=0.514	(e)	(e)
POLY 6	P=0.310	P=0.751N	P=0.544N	P=0.486	P=0.586N	P=0.519	(e)	(e)
LOGISTIC REGRESSION	P=0.322	P=0.763	P=0.500N	P=0.502	(e)	P=0.506	(e)	(e)
COCH-ARM / FISHERS	P=0.318	P=0.753N	P=0.505N	P=0.500	P=0.607N	P=0.505	(e)	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Uterus Polyp Stromal								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)					5/50 (10%)	7/50 (14%)	12/50 (24%)	6/50 (12%)
POLY-3 RATE (b)					5/42.73	7/46.42	12/43.19	6/45.77
POLY-3 PERCENT (g)					11.7%	15.1%	27.8%	13.1%
TERMINAL (d)					5/33 (15%)	7/34 (21%)	8/28 (29%)	4/36 (11%)
FIRST INCIDENCE					730 (T)	730 (T)	559	555
STATISTICAL TESTS								
LIFE TABLE					P=0.413N	P=0.398	P=0.029 *	P=0.559
POLY 3					P=0.453N	P=0.438	P=0.052	P=0.548
POLY 1.5					P=0.466N	P=0.423	P=0.056	P=0.535
POLY 6					P=0.438N	P=0.447	P=0.045 *	P=0.560
LOGISTIC REGRESSION					P=0.468N	P=0.398	P=0.044 *	P=0.539
COCH-ARM / FISHERS					P=0.494N	P=0.380	P=0.054	P=0.500

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Uterus Sarcoma Stromal or Polyp Stromal								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)					5/50 (10%)	7/50 (14%)	12/50 (24%)	6/50 (12%)
POLY-3 RATE (b)					5/42.73	7/46.42	12/43.19	6/45.77
POLY-3 PERCENT (g)					11.7%	15.1%	27.8%	13.1%
TERMINAL (d)					5/33 (15%)	7/34 (21%)	8/28 (29%)	4/36 (11%)
FIRST INCIDENCE					730 (T)	730 (T)	559	555
STATISTICAL TESTS								
LIFE TABLE					P=0.413N	P=0.398	P=0.029 *	P=0.559
POLY 3					P=0.453N	P=0.438	P=0.052	P=0.548
POLY 1.5					P=0.466N	P=0.423	P=0.056	P=0.535
POLY 6					P=0.438N	P=0.447	P=0.045 *	P=0.560
LOGISTIC REGRESSION					P=0.468N	P=0.398	P=0.044 *	P=0.539
COCH-ARM / FISHERS					P=0.494N	P=0.380	P=0.054	P=0.500

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Zymbal's Gland Carcinoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/42.52	2/44.12	0/36.82	2/40.72	2/44.48	1/46.42	1/42.44	0/45.19
POLY-3 PERCENT (g)	2.4%	4.5%	0.0%	4.9%	4.5%	2.2%	2.4%	0.0%
TERMINAL (d)	0/27 (0%)	1/29 (3%)	0/16 (0%)	2/22 (9%)	0/33 (0%)	1/34 (3%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	458	464	---	729 (T)	284	730 (T)	610	---
STATISTICAL TESTS								
LIFE TABLE	P=0.410	P=0.520	P=0.504N	P=0.455	P=0.212N	P=0.489N	P=0.491N	P=0.235N
POLY 3	P=0.441	P=0.513	P=0.529N	P=0.485	P=0.215N	P=0.485N	P=0.516N	P=0.234N
POLY 1.5	P=0.447	P=0.509	P=0.517N	P=0.492	P=0.216N	P=0.489N	P=0.507N	P=0.234N
POLY 6	P=0.429	P=0.517	P=0.546N	P=0.471	P=0.213N	P=0.483N	P=0.531N	P=0.233N
LOGISTIC REGRESSION	P=0.454	P=0.342	P=0.391N	P=0.502	P=0.267N	P=0.706	P=0.735	P=0.442N
COCH-ARM / FISHERS	P=0.451	P=0.500	P=0.500N	P=0.500	P=0.214N	P=0.500N	P=0.500N	P=0.247N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
All Organs Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	33/50 (66%)	31/50 (62%)	35/50 (70%)	27/50 (54%)	24/50 (48%)	24/50 (48%)	28/50 (56%)	20/50 (40%)
POLY-3 RATE (b)	33/47.19	31/46.27	35/45.61	27/45.69	24/45.04	24/47.68	28/47.24	20/47.78
POLY-3 PERCENT (g)	69.9%	67.0%	76.7%	59.1%	53.3%	50.3%	59.3%	41.9%
TERMINAL (d)	16/27 (59%)	19/29 (66%)	12/16 (75%)	13/22 (59%)	15/33 (46%)	17/34 (50%)	13/28 (46%)	13/36 (36%)
FIRST INCIDENCE	296	569	361	254	380	642	507	519
STATISTICAL TESTS								
LIFE TABLE	P=0.437N	P=0.317N	P=0.034 *	P=0.443N	P=0.133N	P=0.490N	P=0.163	P=0.205N
POLY 3	P=0.121N	P=0.466N	P=0.300	P=0.183N	P=0.123N	P=0.469N	P=0.354	P=0.184N
POLY 1.5	P=0.108N	P=0.444N	P=0.329	P=0.162N	P=0.139N	P=0.494N	P=0.340	P=0.207N
POLY 6	P=0.169N	P=0.496N	P=0.248	P=0.241N	P=0.109N	P=0.459N	P=0.357	P=0.167N
LOGISTIC REGRESSION	P=0.118N	P=0.381N	P=0.368	P=0.153N	P=0.170N	P=0.468N	P=0.281	P=0.245N
COCH-ARM / FISHERS	P=0.114N	P=0.418N	P=0.415	P=0.154N	P=0.176N	P=0.579N	P=0.274	P=0.273N

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
All Organs Mesothelioma: Benign, Malignant, NOS								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	3/50 (6%)	4/50 (8%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/42.09	2/44.04	3/37.84	4/41.21	0/42.73	0/46.42	0/42.02	0/45.19
POLY-3 PERCENT (g)	4.8%	4.5%	7.9%	9.7%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	1/27 (4%)	1/29 (3%)	1/16 (6%)	2/22 (9%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	639	509	561	662	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.205	P=0.670N	P=0.368	P=0.283	(e)	(e)	(e)	(e)
POLY 3	P=0.227	P=0.678N	P=0.451	P=0.327	(e)	(e)	(e)	(e)
POLY 1.5	P=0.236	P=0.683N	P=0.471	P=0.333	(e)	(e)	(e)	(e)
POLY 6	P=0.212	P=0.673N	P=0.420	P=0.313	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.245	P=0.671	P=0.510	P=0.328	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.244	P=0.691N	P=0.500	P=0.339	(e)	(e)	(e)	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
All Organs Mesothelioma: Malignant								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	3/50 (6%)	4/50 (8%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/42.09	2/44.04	3/37.84	4/41.21	0/42.73	0/46.42	0/42.02	0/45.19
POLY-3 PERCENT (g)	4.8%	4.5%	7.9%	9.7%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	1/27 (4%)	1/29 (3%)	1/16 (6%)	2/22 (9%)	0/33 (0%)	0/34 (0%)	0/28 (0%)	0/36 (0%)
FIRST INCIDENCE	639	509	561	662	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.205	P=0.670N	P=0.368	P=0.283	(e)	(e)	(e)	(e)
POLY 3	P=0.227	P=0.678N	P=0.451	P=0.327	(e)	(e)	(e)	(e)
POLY 1.5	P=0.236	P=0.683N	P=0.471	P=0.333	(e)	(e)	(e)	(e)
POLY 6	P=0.212	P=0.673N	P=0.420	P=0.313	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.245	P=0.671	P=0.510	P=0.328	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.244	P=0.691N	P=0.500	P=0.339	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

All Organs
Benign Tumors

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	50/50 (100%)	50/50 (100%)	48/50 (96%)	49/50 (98%)	41/50 (82%)	45/50 (90%)	42/50 (84%)	41/50 (82%)
POLY-3 RATE (b)	50/50.00	50/50.00	48/48.12	49/49.04	41/45.13	45/50.00	42/46.79	41/47.85
POLY-3 PERCENT (g)	100.0%	100.0%	99.8%	99.9%	90.8%	90.0%	89.8%	85.7%
TERMINAL (d)	27/27 (100%)	29/29 (100%)	16/16 (100%)	22/22 (100%)	31/33 (94%)	29/34 (85%)	26/28 (93%)	30/36 (83%)
FIRST INCIDENCE	296	464	431	509	537	410	528	555
STATISTICAL TESTS								
LIFE TABLE	P=0.211	(e)	P=0.027 *	P=0.259	P=0.179N	P=0.436	P=0.145	P=0.327N
POLY 3	P=1.000N	(e)	P=1.000N	P=1.000N	P=0.245N	P=0.586N	P=0.580N	P=0.317N
POLY 1.5	P=0.945N	(e)	P=0.967N	P=1.000N	P=0.272N	P=0.524	P=0.587N	P=0.402N
POLY 6	P=1.000N	(e)	P=1.000N	P=1.000N	P=0.222N	P=0.438N	P=0.610N	P=0.247N
LOGISTIC REGRESSION	P=0.598N	(e)	P=0.328N	(e)	P=0.237N	P=0.494	P=0.533	P=0.350N
COCH-ARM / FISHERS	P=0.419N	(e)	P=0.247N	P=0.500N	P=0.354N	P=0.194	P=0.500	P=0.602N

All Organs
Malignant Tumors

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	35/50 (70%)	34/50 (68%)	40/50 (80%)	40/50 (80%)	33/50 (66%)	27/50 (54%)	32/50 (64%)	23/50 (46%)
POLY-3 RATE (b)	35/47.94	34/48.06	40/46.78	40/47.51	33/47.86	27/47.68	32/48.46	23/47.78
POLY-3 PERCENT (g)	73.0%	70.8%	85.5%	84.2%	69.0%	56.6%	66.0%	48.1%
TERMINAL (d)	17/27 (63%)	19/29 (66%)	13/16 (81%)	20/22 (91%)	20/33 (61%)	20/34 (59%)	14/28 (50%)	16/36 (44%)
FIRST INCIDENCE	296	464	361	254	284	642	471	519
STATISTICAL TESTS								
LIFE TABLE	P=0.066	P=0.372N	P=0.010 *	P=0.093	P=0.045N*	P=0.144N	P=0.405	P=0.034N*
POLY 3	P=0.079	P=0.492N	P=0.096	P=0.128	P=0.040N*	P=0.147N	P=0.465N	P=0.028N*
POLY 1.5	P=0.100	P=0.495N	P=0.110	P=0.153	P=0.042N*	P=0.141N	P=0.463N	P=0.029N*
POLY 6	P=0.049 *	P=0.490N	P=0.078	P=0.090	P=0.038N*	P=0.160N	P=0.472N	P=0.029N*
LOGISTIC REGRESSION	P=0.120	P=0.517N	P=0.152	P=0.178	P=0.050N	P=0.140N	P=0.505N	P=0.038N*
COCH-ARM / FISHERS	P=0.122	P=0.500N	P=0.178	P=0.178	P=0.047N*	P=0.154N	P=0.500N	P=0.035N*

Statistical Analysis of Primary Tumors in Rats(FISCHER 344) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
All Organs								
Malignant and Benign Tumors								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	50/50 (100%)	50/50 (100%)	49/50 (98%)	50/50 (100%)	49/50 (98%)	48/50 (96%)	50/50 (100%)	45/50 (90%)
POLY-3 RATE (b)	50/50.00	50/50.00	49/49.00	50/50.00	49/49.01	48/50.00	50/50.00	45/49.06
POLY-3 PERCENT (g)	100.0%	100.0%	100.0%	100.0%	100.0%	96.0%	100.0%	91.7%
TERMINAL (d)	27/27 (100%)	29/29 (100%)	16/16 (100%)	22/22 (100%)	33/33 (100%)	32/34 (94%)	28/28 (100%)	32/36 (89%)
FIRST INCIDENCE	296	464	361	254	284	410	471	519
STATISTICAL TESTS								
LIFE TABLE	P=0.173	(e)	P=0.021 *	(e)	P=0.092N	P=0.339N	P=0.163	P=0.120N
POLY 3	P=1.000	(e)	P=1.000N	(e)	P=0.028N*	P=0.245N	P=1.000	P=0.058N
POLY 1.5	P=1.000	(e)	P=1.000N	(e)	P=0.023N*	P=0.269N	P=1.000	P=0.055N
POLY 6	P=1.000	(e)	P=1.000N	(e)	P=0.030N*	P=0.242N	P=1.000	P=0.061N
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.016N*	P=0.273N	(e)	P=0.038N*
COCH-ARM / FISHERS	P=0.772	(e)	P=0.500N	(e)	P=0.027N*	P=0.500N	P=0.500	P=0.102N

(a) Number of tumor-bearing animals / number of animals examined at site.
(b) Number of tumor-bearing animals / Poly-3 number
(d) Observed incidence at terminal kill.
(f) 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.
Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors. The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates
For all tests a negative trend is indicated by N
(e) Value of Statistic cannot be computed.
(g) Poly-3 adjusted lifetime tumor incidence.
(I) Interim sacrifice
(T) Terminal sacrifice
Tumor rates based on number of animals necropsied.
* To the right of any statistical result, indicates significance at (P<=0.05).
** To the right of any statistical result, indicates significance at (P<=0.01).

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FINAL/MICE

Facility: Battelle Northwest

Chemical CAS #: 57018-52-7

Lock Date: 12/11/00

Cage Range: All

Reasons For Removal: All

Removal Date Range: All

Treatment Groups: Include All

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
DISPOSITION SUMMARY				
Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	8	10	6	4
Natural Death	3	3	2	6
Accidently Killed		1		1
Survivors				
Terminal Sacrifice	39	36	41	38
Natural Death			1	1
Animals Examined Microscopically	50	50	50	49
ALIMENTARY SYSTEM				
Gallbladder	(40)	(39)	(43)	(33)
Cyst	1 (3%)			
Intestine Large, Colon	(48)	(49)	(50)	(48)
Infiltration Cellular, Mixed Cell				1 (2%)
Intestine Large, Rectum	(48)	(49)	(50)	(48)
Necrosis				1 (2%)
Intestine Large, Cecum	(49)	(48)	(49)	(46)
Necrosis			2 (4%)	
Intestine Small, Duodenum	(49)	(47)	(50)	(46)
Infiltration Cellular, Mixed Cell				1 (2%)
Epithelium, Hyperplasia			1 (2%)	
Intestine Small, Jejunum	(49)	(48)	(48)	(47)
Infiltration Cellular, Mixed Cell			1 (2%)	
Inflammation, Suppurative				1 (2%)
Necrosis				1 (2%)
Intestine Small, Ileum	(49)	(48)	(48)	(45)
Hyperplasia	1 (2%)			
Infiltration Cellular, Mixed Cell	2 (4%)	1 (2%)	3 (6%)	1 (2%)
Necrosis				2 (4%)
Epithelium, Hyperplasia	1 (2%)			
Liver	(49)	(50)	(50)	(49)
Angiectasis			1 (2%)	
Basophilic Focus	3 (6%)	4 (8%)	4 (8%)	2 (4%)
Clear Cell Focus	4 (8%)	4 (8%)	6 (12%)	5 (10%)
Eosinophilic Focus	11 (22%)	10 (20%)	9 (18%)	27 (55%)
Fatty Change	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Fatty Change, Focal		1 (2%)		
Hematopoietic Cell Proliferation			1 (2%)	

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
ALIMENTARY SYSTEM - CONT				
Infarct			1 (2%)	
Inflammation, Granulomatous	23 (47%)	9 (18%)	17 (34%)	12 (24%)
Tension Lipidosis	4 (8%)	3 (6%)	6 (12%)	4 (8%)
Thrombosis			1 (2%)	
Bile Duct, Cyst	1 (2%)			
Bile Duct, Hyperplasia		1 (2%)	1 (2%)	
Centrilobular, Necrosis		3 (6%)		
Hepatocyte, Mitotic Alteration		1 (2%)		
Mesentery	(17)	(21)	(13)	(2)
Infiltration Cellular, Mast Cell	1 (6%)			
Fat, Congestion	1 (6%)			
Fat, Necrosis	14 (82%)	19 (90%)	12 (92%)	2 (100%)
Oral Mucosa	(1)			
Inflammation	1 (100%)			
Pancreas	(49)	(50)	(50)	(48)
Atrophy	1 (2%)		2 (4%)	
Basophilic Focus	1 (2%)	1 (2%)	1 (2%)	
Duct, Cyst			1 (2%)	
Salivary Glands	(50)	(50)	(50)	(49)
Atrophy				1 (2%)
Stomach, Forestomach	(49)	(50)	(50)	(48)
Hyperplasia, Squamous	3 (6%)	5 (10%)	1 (2%)	6 (13%)
Infiltration Cellular, Mast Cell			1 (2%)	
Infiltration Cellular, Mixed Cell	1 (2%)			
Inflammation	2 (4%)	5 (10%)	2 (4%)	6 (13%)
Ulcer	2 (4%)		1 (2%)	4 (8%)
Stomach, Glandular	(49)	(48)	(50)	(48)
Mineralization	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Tooth	(50)	(50)	(50)	(49)
Inflammation, Chronic Active	1 (2%)	2 (4%)	1 (2%)	7 (14%)
Malformation	1 (2%)	1 (2%)		
CARDIOVASCULAR SYSTEM				
Blood Vessel			(2)	
Inflammation, Chronic			1 (50%)	
Heart	(50)	(50)	(50)	(49)
Cardiomyopathy	5 (10%)	4 (8%)	8 (16%)	3 (6%)
Inflammation, Chronic		1 (2%)		
Mineralization	1 (2%)	1 (2%)		
Thrombosis				1 (2%)
Artery, Inflammation, Chronic Active	1 (2%)			

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
CARDIOVASCULAR SYSTEM - CONT				
Endocardium, Hyperplasia		1 (2%)		
Valve, Inflammation, Suppurative		1 (2%)		
ENDOCRINE SYSTEM				
Adrenal Cortex	(49)	(50)	(50)	(48)
Hyperplasia	8 (16%)	3 (6%)	3 (6%)	4 (8%)
Hypertrophy	7 (14%)	7 (14%)	1 (2%)	2 (4%)
Necrosis	1 (2%)	1 (2%)		
Vacuolization Cytoplasmic		3 (6%)	3 (6%)	
Adrenal Medulla	(47)	(49)	(50)	(48)
Hyperplasia	2 (4%)	4 (8%)	1 (2%)	3 (6%)
Hypertrophy				1 (2%)
Necrosis	1 (2%)			
Islets, Pancreatic	(49)	(50)	(50)	(48)
Hyperplasia	1 (2%)			1 (2%)
Pituitary Gland	(48)	(49)	(47)	(46)
Pars Distalis, Angiectasis	1 (2%)		1 (2%)	1 (2%)
Pars Distalis, Hyperplasia	16 (33%)	11 (22%)	16 (34%)	11 (24%)
Thyroid Gland	(49)	(50)	(50)	(48)
Follicular Cell, Hyperplasia	2 (4%)	1 (2%)	3 (6%)	1 (2%)
GENERAL BODY SYSTEM				
Peritoneum		(1)	(2)	
Inflammation, Chronic, Suppurative		1 (100%)		
GENITAL SYSTEM				
Clitoral Gland	(42)	(43)	(48)	(45)
Inflammation, Chronic		1 (2%)		
Ovary	(50)	(49)	(49)	(48)
Angiectasis	1 (2%)	1 (2%)		
Atrophy				1 (2%)
Cyst	12 (24%)	12 (24%)	12 (24%)	11 (23%)
Inflammation, Chronic Active		1 (2%)		
Thrombosis			1 (2%)	
Uterus	(50)	(50)	(50)	(48)
Angiectasis	3 (6%)	1 (2%)	4 (8%)	2 (4%)
Inflammation, Suppurative		1 (2%)	2 (4%)	2 (4%)

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
GENITAL SYSTEM - CONT				
Thrombosis		2 (4%)		
Endometrium, Fibrosis	1 (2%)			
Endometrium, Hyperplasia, Cystic	46 (92%)	48 (96%)	48 (96%)	45 (94%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(49)	(50)	(50)	(48)
Thrombosis				1 (2%)
Lymph Node	(4)	(8)	(6)	(2)
Angiectasis		2 (25%)		
Ectasia			1 (17%)	
Lumbar, Angiectasis	1 (25%)			
Renal, Angiectasis	1 (25%)			
Renal, Ectasia	1 (25%)			
Lymph Node, Mandibular	(44)	(45)	(45)	(34)
Hyperplasia, Lymphoid				1 (3%)
Infiltration Cellular, Plasma Cell				1 (3%)
Lymph Node, Mesenteric	(48)	(48)	(48)	(48)
Angiectasis	1 (2%)	2 (4%)	2 (4%)	1 (2%)
Infiltration Cellular, Plasma Cell		1 (2%)		
Inflammation, Granulomatous			1 (2%)	
Inflammation, Suppurative				1 (2%)
Lymph Node, Mediastinal	(40)	(41)	(41)	(31)
Hemorrhage	1 (3%)			
Spleen	(49)	(50)	(50)	(48)
Fibrosis		1 (2%)		
Hematopoietic Cell Proliferation	4 (8%)	4 (8%)	2 (4%)	3 (6%)
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(49)
Hyperplasia, Squamous	1 (2%)			
Infiltration Cellular, Mixed Cell	1 (2%)	3 (6%)	2 (4%)	
Inflammation, Acute				1 (2%)
Inflammation, Chronic Active				1 (2%)
Subcutaneous Tissue, Inflammation, Acute		1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(49)

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
MUSCULOSKELETAL SYSTEM - CONT				
Synovial Tissue, Hyperplasia			1 (2%)	
Skeletal Muscle	(1)	(2)		
Hemorrhage	1 (100%)			
Inflammation, Acute		1 (50%)		
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(49)
Meninges, Infiltration Cellular, Mononuclear Cell	1 (2%)			
Spinal Cord	(2)			
Hemorrhage	1 (50%)			
RESPIRATORY SYSTEM				
Larynx	(50)	(50)	(50)	(48)
Metaplasia, Squamous	1 (2%)			
Lung	(50)	(50)	(50)	(49)
Foreign Body			1 (2%)	
Inflammation, Granulomatous				2 (4%)
Mineralization			1 (2%)	
Thrombosis	1 (2%)			2 (4%)
Alveolar Epithelium, Hyperplasia	3 (6%)	2 (4%)	4 (8%)	3 (6%)
Alveolus, Infiltration Cellular, Histiocyte	2 (4%)	1 (2%)		3 (6%)
Artery, Inflammation, Acute				2 (4%)
Nose	(50)	(50)	(49)	(49)
Inflammation, Acute		1 (2%)		
Inflammation, Suppurative	3 (6%)		1 (2%)	1 (2%)
Respiratory Epithelium, Metaplasia, Squamous	2 (4%)			
Respiratory Epithelium, Necrosis	2 (4%)			1 (2%)
Pleura		(1)	(1)	
Hyperplasia		1 (100%)		
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(48)
Cataract				2 (4%)
Anterior Chamber, Inflammation, Acute	1 (2%)			1 (2%)
Cornea, Erosion				3 (6%)
Cornea, Hyperplasia, Squamous	1 (2%)	2 (4%)		2 (4%)

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
SPECIAL SENSES SYSTEM - CONT				
Cornea, Inflammation, Acute				1 (2%)
Cornea, Inflammation, Chronic Active	1 (2%)	2 (4%)		4 (8%)
Cornea, Mineralization	1 (2%)	2 (4%)		20 (42%)
Cornea, Ulcer		1 (2%)		1 (2%)
Retrobulbar, Inflammation, Granulomatous				1 (2%)
Harderian Gland	(50)	(50)	(50)	(49)
Hyperplasia	3 (6%)	3 (6%)	4 (8%)	4 (8%)
URINARY SYSTEM				
Kidney	(49)	(50)	(50)	(48)
Infarct	1 (2%)		2 (4%)	3 (6%)
Metaplasia, Osseous	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Nephropathy	34 (69%)	34 (68%)	32 (64%)	34 (71%)
Thrombosis			1 (2%)	
Pelvis, Dilatation			1 (2%)	
Renal Tubule, Degeneration, Hyaline	1 (2%)			1 (2%)
Renal Tubule, Necrosis			1 (2%)	
Urinary Bladder	(50)	(49)	(50)	(47)
Inflammation, Acute				1 (2%)
Transitional Epithelium, Hyperplasia	1 (2%)			

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
DISPOSITION SUMMARY				
Animals Initially In Study	50	50	50	50
Early Deaths				
Natural Death	11	4	4	5
Moribund Sacrifice	4	6	6	8
Survivors				
Terminal Sacrifice	35	40	40	37
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Gallbladder	(38)	(41)	(39)	(40)
Degeneration, Hyaline		1 (2%)	2 (5%)	
Intestine Large, Colon	(46)	(48)	(48)	(47)
Serosa, Inflammation, Granulomatous		1 (2%)		
Intestine Large, Rectum	(46)	(48)	(48)	(46)
Infiltration Cellular, Mixed Cell	1 (2%)			
Intestine Large, Cecum	(43)	(47)	(48)	(48)
Necrosis	1 (2%)	1 (2%)		
Intestine Small, Jejunum	(42)	(47)	(47)	(45)
Infiltration Cellular, Mixed Cell	2 (5%)		2 (4%)	
Inflammation, Granulomatous	1 (2%)	1 (2%)		
Necrosis			1 (2%)	
Epithelium, Hyperplasia	1 (2%)			
Intestine Small, Ileum	(43)	(47)	(46)	(46)
Infiltration Cellular, Mixed Cell	4 (9%)	2 (4%)	2 (4%)	1 (2%)
Inflammation, Acute			1 (2%)	
Inflammation, Chronic Active		1 (2%)	1 (2%)	
Necrosis			1 (2%)	
Epithelium, Hyperplasia	1 (2%)	1 (2%)		
Liver	(50)	(49)	(50)	(50)
Basophilic Focus	6 (12%)	11 (22%)	16 (32%)	4 (8%)
Clear Cell Focus	20 (40%)	18 (37%)	16 (32%)	17 (34%)
Eosinophilic Focus	9 (18%)	14 (29%)	11 (22%)	29 (58%)
Fatty Change		1 (2%)		2 (4%)
Hematopoietic Cell Proliferation	1 (2%)	1 (2%)	1 (2%)	
Infarct	2 (4%)	1 (2%)	1 (2%)	3 (6%)
Inflammation, Granulomatous	9 (18%)	12 (24%)	11 (22%)	3 (6%)
Mixed Cell Focus				4 (8%)
Tension Lipidosis	1 (2%)	2 (4%)	4 (8%)	2 (4%)
Centrilobular, Necrosis	1 (2%)	1 (2%)	1 (2%)	

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
ALIMENTARY SYSTEM - CONT				
Hepatocyte, Multinucleated	27 (54%)	23 (47%)	24 (48%)	46 (92%)
Mesentery	(14)	(16)	(13)	(11)
Inflammation, Granulomatous	2 (14%)	1 (6%)	4 (31%)	1 (9%)
Artery, Inflammation			1 (8%)	2 (18%)
Fat, Necrosis	10 (71%)	14 (88%)	7 (54%)	7 (64%)
Pancreas	(48)	(49)	(50)	(50)
Atrophy		1 (2%)		
Basophilic Focus				1 (2%)
Stomach, Forestomach	(48)	(49)	(50)	(50)
Hyperkeratosis			1 (2%)	
Hyperplasia, Squamous				1 (2%)
Inflammation	2 (4%)	3 (6%)	9 (18%)	9 (18%)
Ulcer				1 (2%)
Artery, Inflammation, Chronic Active			1 (2%)	
Epithelium, Hyperplasia, Squamous	2 (4%)	5 (10%)	9 (18%)	7 (14%)
Epithelium, Ulcer	1 (2%)	1 (2%)	3 (6%)	3 (6%)
Stomach, Glandular	(46)	(48)	(50)	(48)
Hyperplasia	1 (2%)			
Metaplasia, Squamous	1 (2%)			
Mineralization	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Necrosis		2 (4%)	1 (2%)	
Tooth	(50)	(50)	(50)	(50)
Inflammation, Chronic Active	3 (6%)	5 (10%)	4 (8%)	15 (30%)
Malformation	24 (48%)	15 (30%)	15 (30%)	16 (32%)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	9 (18%)	8 (16%)	11 (22%)	7 (14%)
Mineralization	1 (2%)	1 (2%)		
Necrosis	2 (4%)			
Thrombosis			1 (2%)	1 (2%)
Artery, Inflammation, Chronic Active			3 (6%)	
ENDOCRINE SYSTEM				
Adrenal Cortex	(48)	(49)	(50)	(50)
Hyperplasia	11 (23%)	9 (18%)	14 (28%)	7 (14%)
Hypertrophy	34 (71%)	32 (65%)	29 (58%)	18 (36%)
Adrenal Medulla	(47)	(49)	(49)	(49)
Hyperplasia		1 (2%)	1 (2%)	2 (4%)

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
ENDOCRINE SYSTEM - CONT				
Infiltration Cellular, Polymorphonuclear			1 (2%)	
Islets, Pancreatic	(48)	(49)	(50)	(50)
Hyperplasia		1 (2%)		
Pituitary Gland	(43)	(48)	(50)	(48)
Cyst		1 (2%)		
Pars Distalis, Hyperplasia		1 (2%)	4 (8%)	1 (2%)
Thyroid Gland	(48)	(48)	(49)	(49)
Follicular Cell, Hyperplasia			1 (2%)	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm	1 (2%)	1 (2%)		
Inflammation, Chronic		1 (2%)		
Preputial Gland	(50)	(50)	(50)	(50)
Ectasia	2 (4%)	1 (2%)	1 (2%)	
Hyperplasia, Squamous	1 (2%)			2 (4%)
Inflammation, Chronic		2 (4%)	2 (4%)	
Inflammation, Suppurative		3 (6%)	2 (4%)	2 (4%)
Prostate	(49)	(49)	(47)	(50)
Inflammation, Suppurative			1 (2%)	
Artery, Inflammation, Chronic Active		1 (2%)	1 (2%)	
Seminal Vesicle	(47)	(49)	(49)	(49)
Inflammation, Chronic		2 (4%)	1 (2%)	
Testes	(50)	(50)	(50)	(50)
Amyloid Deposition		1 (2%)		
Atrophy		1 (2%)	1 (2%)	
Mineralization	1 (2%)			
Germinal Epithelium, Degeneration	1 (2%)			1 (2%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(49)	(49)	(50)	(50)
Thrombosis				1 (2%)
Lymph Node, Bronchial	(32)	(36)	(36)	(35)
Infiltration Cellular, Plasma Cell	1 (3%)			

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
HEMATOPOIETIC SYSTEM - CONT				
Lymph Node, Mandibular	(28)	(38)	(30)	(25)
Infiltration Cellular, Plasma Cell				1 (4%)
Lymph Node, Mesenteric	(48)	(49)	(49)	(50)
Angiectasis			1 (2%)	
Infiltration Cellular, Plasma Cell	2 (4%)	1 (2%)	4 (8%)	
Infiltration Cellular, Mixed Cell	1 (2%)			
Pigmentation		1 (2%)		
Lymph Node, Mediastinal	(39)	(39)	(43)	(36)
Inflammation, Granulomatous		1 (3%)		
Spleen	(48)	(48)	(50)	(50)
Angiectasis				1 (2%)
Hematopoietic Cell Proliferation	4 (8%)	2 (4%)	2 (4%)	2 (4%)
Hyperplasia, Lymphoid				1 (2%)
Infiltration Cellular, Histiocyte	1 (2%)			
INTEGUMENTARY SYSTEM				
Skin	(49)	(50)	(50)	(50)
Infiltration Cellular, Mixed Cell		1 (2%)		
Inflammation, Chronic Active	4 (8%)	1 (2%)	6 (12%)	5 (10%)
Epidermis, Hyperplasia				1 (2%)
Subcutaneous Tissue, Edema	1 (2%)			
Subcutaneous Tissue, Hemorrhage	1 (2%)			
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Fibrous Osteodystrophy	1 (2%)			
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Necrosis	1 (2%)			
Artery, Inflammation, Chronic Active			1 (2%)	
RESPIRATORY SYSTEM				
Larynx	(49)	(50)	(50)	(50)
Artery, Inflammation, Chronic Active			1 (2%)	

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
RESPIRATORY SYSTEM - CONT				
Lung	(50)	(50)	(50)	(50)
Hemorrhage		1 (2%)		1 (2%)
Inflammation, Granulomatous		1 (2%)		1 (2%)
Inflammation, Suppurative			1 (2%)	
Mineralization		1 (2%)		
Thrombosis		3 (6%)		
Alveolar Epithelium, Hyperplasia	6 (12%)	4 (8%)	4 (8%)	
Alveolus, Infiltration Cellular, Histiocyte	1 (2%)			2 (4%)
Nose	(50)	(49)	(50)	(50)
Amyloid Deposition		1 (2%)		
Inflammation, Suppurative	5 (10%)		4 (8%)	6 (12%)
Olfactory Epithelium, Atrophy			1 (2%)	
Respiratory Epithelium, Metaplasia, Squamous				1 (2%)
Respiratory Epithelium, Necrosis			1 (2%)	1 (2%)
Pleura	(1)		(1)	
Necrosis, Fatty			1 (100%)	
Trachea	(48)	(48)	(50)	(50)
Degeneration, Hyaline			1 (2%)	
Inflammation, Suppurative			1 (2%)	
SPECIAL SENSES SYSTEM				
Eye	(48)	(49)	(50)	(50)
Cornea, Erosion				1 (2%)
Cornea, Hyperplasia, Squamous	1 (2%)			1 (2%)
Cornea, Inflammation, Chronic Active	1 (2%)		1 (2%)	1 (2%)
Cornea, Mineralization				3 (6%)
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia	10 (20%)	3 (6%)	5 (10%)	1 (2%)
Zymbal's Gland	(35)	(35)	(36)	(32)
Hyperplasia	1 (3%)			
URINARY SYSTEM				
Kidney	(50)	(49)	(50)	(50)
Amyloid Deposition		1 (2%)		
Cyst	1 (2%)	1 (2%)	2 (4%)	
Infarct	3 (6%)	3 (6%)	3 (6%)	7 (14%)
Inflammation, Chronic, Suppurative		1 (2%)		1 (2%)
Metaplasia, Osseous	3 (6%)	6 (12%)	2 (4%)	
Mineralization		1 (2%)		

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
URINARY SYSTEM - CONT				
Nephropathy	41 (82%)	40 (82%)	44 (88%)	36 (72%)
Artery, Inflammation, Chronic Active			2 (4%)	1 (2%)
Papilla, Inflammation, Suppurative			1 (2%)	
Pelvis, Dilatation			1 (2%)	2 (4%)
Renal Tubule, Hyperplasia	2 (4%)		1 (2%)	
Renal Tubule, Necrosis	1 (2%)			
Transitional Epithelium, Hyperplasia				2 (4%)
Urinary Bladder	(48)	(48)	(49)	(50)
Inflammation, Chronic Active			1 (2%)	
Artery, Inflammation, Chronic Active		1 (2%)	1 (2%)	

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

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---------- END OF REPORT ----------

FINAL/MICE

Facility: Battelle Northwest

Chemical CAS #: 57018-52-7

Lock Date: 12/11/00

Cage Range: All

Reasons For Removal: All

Removal Date Range: All

Treatment Groups: Include All

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

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
DISPOSITION SUMMARY				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	8	10	6	4
Natural Death	3	3	2	6
Accidently Killed		1		1
Survivors				
Terminal Sacrifice	39	36	41	38
Natural Death			1	1
Animals Examined Microscopically	50	50	50	49
ALIMENTARY SYSTEM				
Gallbladder	(40)	(39)	(43)	(33)
Histiocytic Sarcoma			1 (2%)	
Intestine Large, Colon	(48)	(49)	(50)	(48)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Histiocytic Sarcoma			1 (2%)	
Intestine Large, Rectum	(48)	(49)	(50)	(48)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Intestine Large, Cecum	(49)	(48)	(49)	(46)
Histiocytic Sarcoma			1 (2%)	
Leiomyoma				1 (2%)
Intestine Small, Duodenum	(49)	(47)	(50)	(46)
Histiocytic Sarcoma			1 (2%)	
Intestine Small, Jejunum	(49)	(48)	(48)	(47)
Carcinoma				1 (2%)
Intestine Small, Ileum	(49)	(48)	(48)	(45)
Carcinoma	1 (2%)			
Sarcoma, Metastatic, Skin		1 (2%)		
Liver	(49)	(50)	(50)	(49)
Cholangioma				1 (2%)
Hemangioma				1 (2%)
Hemangiosarcoma		2 (4%)		
Hepatoblastoma				2 (4%)
Hepatocellular Carcinoma	4 (8%)	8 (16%)	6 (12%)	8 (16%)
Hepatocellular Carcinoma, Multiple			1 (2%)	2 (4%)
Hepatocellular Adenoma	8 (16%)	8 (16%)	7 (14%)	5 (10%)
Hepatocellular Adenoma, Multiple	6 (12%)		3 (6%)	32 (65%)
Hepatocholangiocarcinoma			1 (2%)	

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
ALIMENTARY SYSTEM - cont				
Histiocytic Sarcoma	1 (2%)		1 (2%)	1 (2%)
Mesentery	(17)	(21)	(13)	(2)
Hemangiosarcoma	1 (6%)			
Hepatocholangiocarcinoma, Metastatic, Liver			1 (8%)	
Pancreas	(49)	(50)	(50)	(48)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Histiocytic Sarcoma			1 (2%)	
Salivary Glands	(50)	(50)	(50)	(49)
Stomach, Forestomach	(49)	(50)	(50)	(48)
Histiocytic Sarcoma			1 (2%)	
Squamous Cell Papilloma			1 (2%)	1 (2%)
Stomach, Glandular	(49)	(48)	(50)	(48)
Histiocytic Sarcoma			1 (2%)	
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(49)
Sarcoma, Metastatic, Uncertain Primary Site			1 (2%)	
ENDOCRINE SYSTEM				
Adrenal Cortex	(49)	(50)	(50)	(48)
Carcinoma	1 (2%)			
Hepatocellular Carcinoma, Metastatic, Liver		1 (2%)		
Adrenal Medulla	(47)	(49)	(50)	(48)
Pheochromocytoma Malignant		1 (2%)		
Islets, Pancreatic	(49)	(50)	(50)	(48)
Adenoma	1 (2%)			
Pituitary Gland	(48)	(49)	(47)	(46)
Pars Distalis, Adenoma	9 (19%)	11 (22%)	12 (26%)	8 (17%)
Pars Intermedia, Adenoma		1 (2%)	1 (2%)	
GENERAL BODY SYSTEM				
Peritoneum		(1)	(2)	
Hepatocholangiocarcinoma, Metastatic, Liver			1 (50%)	
Histiocytic Sarcoma			1 (50%)	

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
GENITAL SYSTEM				
Ovary	(50)	(49)	(49)	(48)
Carcinoma		1 (2%)		
Cystadenoma	2 (4%)	1 (2%)	3 (6%)	1 (2%)
Histiocytic Sarcoma			1 (2%)	
Luteoma	2 (4%)		1 (2%)	1 (2%)
Uterus	(50)	(50)	(50)	(48)
Adenoma	1 (2%)			
Hemangiosarcoma			2 (4%)	
Histiocytic Sarcoma			1 (2%)	
Leiomyoma			2 (4%)	
Leiomyosarcoma				1 (2%)
Polyp Stromal		1 (2%)	1 (2%)	
Sarcoma Stromal	1 (2%)			
HEMATOPOIETIC SYSTEM				
Bone Marrow	(49)	(50)	(50)	(48)
Hemangiosarcoma		1 (2%)		
Histiocytic Sarcoma				1 (2%)
Lymph Node	(4)	(8)	(6)	(2)
Lumbar, Hemangiosarcoma			1 (17%)	
Lymph Node, Bronchial	(45)	(34)	(44)	(42)
Histiocytic Sarcoma	1 (2%)			
Lymph Node, Mandibular	(44)	(45)	(45)	(34)
Histiocytic Sarcoma				1 (3%)
Lymph Node, Mesenteric	(48)	(48)	(48)	(48)
Histiocytic Sarcoma			1 (2%)	1 (2%)
Lymph Node, Mediastinal	(40)	(41)	(41)	(31)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		1 (2%)		
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Histiocytic Sarcoma	1 (3%)		1 (2%)	
Spleen	(49)	(50)	(50)	(48)
Hemangiosarcoma		1 (2%)		
Histiocytic Sarcoma	1 (2%)		1 (2%)	1 (2%)
Thymus	(45)	(45)	(46)	(42)
Sarcoma, Metastatic, Uncertain Primary Site			1 (2%)	

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(49)
Subcutaneous Tissue, Hemangiosarcoma		1 (2%)		
Subcutaneous Tissue, Mast Cell Tumor Benign		1 (2%)		
Subcutaneous Tissue, Sarcoma	1 (2%)	7 (14%)	1 (2%)	2 (4%)
Subcutaneous Tissue, Sarcoma, Multiple		1 (2%)		
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(49)
Histiocytic Sarcoma				1 (2%)
RESPIRATORY SYSTEM				
Larynx	(50)	(50)	(50)	(48)
Lung	(50)	(50)	(50)	(49)
Alveolar/Bronchiolar Adenoma	2 (4%)	2 (4%)	2 (4%)	
Alveolar/Bronchiolar Carcinoma	1 (2%)	3 (6%)		1 (2%)
Alveolar/Bronchiolar Carcinoma, Multiple			1 (2%)	
Carcinoma, Metastatic, Harderian Gland		1 (2%)		2 (4%)
Carcinoma, Metastatic, Ovary		1 (2%)		
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)	4 (8%)	2 (4%)	3 (6%)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Histiocytic Sarcoma	1 (2%)		1 (2%)	1 (2%)
Sarcoma, Metastatic, Skin			1 (2%)	
Sarcoma, Metastatic, Uncertain Primary Site			1 (2%)	
Nose	(50)	(50)	(49)	(49)
Carcinoma, Metastatic, Harderian Gland		1 (2%)		
Pleura		(1)	(1)	
Sarcoma, Metastatic, Uncertain Primary Site			1 (100%)	

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(48)
Carcinoma, Metastatic, Harderian Gland		1 (2%)		1 (2%)
Harderian Gland	(50)	(50)	(50)	(49)
Adenoma	3 (6%)	4 (8%)	5 (10%)	3 (6%)
Carcinoma		2 (4%)		2 (4%)
Bilateral, Adenoma				1 (2%)
URINARY SYSTEM				
Kidney	(49)	(50)	(50)	(48)
Histiocytic Sarcoma			1 (2%)	
Urinary Bladder	(50)	(49)	(50)	(47)
Histiocytic Sarcoma			1 (2%)	
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(49)
Histiocytic Sarcoma	1 (2%)		1 (2%)	1 (2%)
Lymphoma Malignant	13 (26%)	15 (30%)	10 (20%)	7 (14%)

* Number of animals with any tissue examined microscopically

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
TUMOR SUMMARY				
Total Animals with Primary Neoplasms (b)	37	39	36	47
Total Primary Neoplasms	58	72	62	82
Total Animals with Benign Neoplasms	25	24	28	39
Total Benign Neoplasms	34	29	38	55
Total Animals with Malignant Neoplasms	23	30	20	22
Total Malignant Neoplasms	24	43	24	27
Total Animals with Metastatic Neoplasms	1	8	5	5
Total Metastatic Neoplasm	1	11	14	6
Total Animals with Malignant Neoplasms Uncertain Primary Site			1	
Total Animals with Neoplasms Uncertain-Benign or Malignant				
Total Uncertain Neoplasms				

a Number of animals examined microscopically at site and number of animals with lesion
b Primary tumors: all tumors except metastatic tumors

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
DISPOSITION SUMMARY				
Animals Initially in Study	50	50	50	50
Early Deaths				
Natural Death	11	4	4	5
Moribund Sacrifice	4	6	6	8
Survivors				
Terminal Sacrifice	35	40	40	37
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Gallbladder	(38)	(41)	(39)	(40)
Sarcoma, Metastatic, Mesentery			1 (3%)	
Intestine Large, Cecum	(43)	(47)	(48)	(48)
Carcinoma, Metastatic, Intestine Small, Jejunum	1 (2%)			
Polyp Adenomatous				1 (2%)
Intestine Small, Duodenum	(43)	(48)	(47)	(44)
Polyp Adenomatous		2 (4%)	1 (2%)	
Intestine Small, Jejunum	(42)	(47)	(47)	(45)
Carcinoma	2 (5%)	1 (2%)	1 (2%)	1 (2%)
Polyp Adenomatous	1 (2%)		1 (2%)	1 (2%)
Intestine Small, Ileum	(43)	(47)	(46)	(46)
Carcinoma			1 (2%)	
Liver	(50)	(49)	(50)	(50)
Hemangiosarcoma	2 (4%)		1 (2%)	1 (2%)
Hepatoblastoma			1 (2%)	5 (10%)
Hepatocellular Carcinoma	8 (16%)	7 (14%)	11 (22%)	9 (18%)
Hepatocellular Carcinoma, Multiple	1 (2%)	1 (2%)	2 (4%)	2 (4%)
Hepatocellular Adenoma	15 (30%)	16 (33%)	14 (28%)	13 (26%)
Hepatocellular Adenoma, Multiple	3 (6%)	7 (14%)	12 (24%)	23 (46%)
Histiocytic Sarcoma		1 (2%)		
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Plasma Cell Tumor Malignant, Metastatic, Uncertain Primary Site	1 (2%)			
Sarcoma, Metastatic, Mesentery			1 (2%)	
Mesentery	(14)	(16)	(13)	(11)
Carcinoma, Metastatic, Intestine Small, Jejunum	1 (7%)			

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
ALIMENTARY SYSTEM - cont				
Hemangiosarcoma		2 (13%)		
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (7%)			
Sarcoma			1 (8%)	
Pancreas	(48)	(49)	(50)	(50)
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Plasma Cell Tumor Malignant, Metastatic, Uncertain Primary Site	1 (2%)			
Sarcoma, Metastatic, Mesentery			1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(48)	(49)	(50)	(50)
Carcinoma, Metastatic, Intestine Small, Jejunum	1 (2%)			
Mast Cell Tumor Malignant, Metastatic, Bone Marrow			1 (2%)	
Epithelium, Squamous Cell Carcinoma		1 (2%)		
Epithelium, Squamous Cell Papilloma			1 (2%)	
Stomach, Glandular	(46)	(48)	(50)	(48)
Mast Cell Tumor Malignant, Metastatic, Bone Marrow			1 (2%)	
Sarcoma, Metastatic, Mesentery			1 (2%)	
Tongue				(1)
Squamous Cell Papilloma				1 (100%)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Intestine Small, Jejunum	1 (2%)			
Hemangiosarcoma		1 (2%)		
ENDOCRINE SYSTEM				
Adrenal Cortex	(48)	(49)	(50)	(50)
Adenoma				1 (2%)
Carcinoma		1 (2%)		
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Sarcoma, Metastatic, Mesentery			1 (2%)	
Capsule, Adenoma				1 (2%)

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
ENDOCRINE SYSTEM - cont				
Subcapsular, Adenoma	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Subcapsular, Carcinoma		1 (2%)		
Adrenal Medulla	(47)	(49)	(49)	(49)
Pheochromocytoma Benign			1 (2%)	
Islets, Pancreatic	(48)	(49)	(50)	(50)
Adenoma	2 (4%)			
Thyroid Gland	(48)	(48)	(49)	(49)
Follicular Cell, Adenoma	1 (2%)		1 (2%)	
Follicular Cell, Carcinoma			1 (2%)	
GENERAL BODY SYSTEM				
Peritoneum	(2)			
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (50%)			
Plasma Cell Tumor Malignant, Metastatic, Uncertain Primary Site	1 (50%)			
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Prostate	(49)	(49)	(47)	(50)
Adenoma	1 (2%)			
Seminal Vesicle	(47)	(49)	(49)	(49)
Adenoma		1 (2%)		
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Plasma Cell Tumor Malignant, Metastatic, Uncertain Primary Site	1 (2%)			
Sarcoma, Metastatic, Mesentery			1 (2%)	
Testes	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Intestine Small, Jejunum	1 (2%)			
Hemangioma	1 (2%)			
Interstitial Cell, Adenoma	2 (4%)		2 (4%)	

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
HEMATOPOIETIC SYSTEM				
Bone Marrow	(49)	(49)	(50)	(50)
Mast Cell Tumor Malignant			1 (2%)	
Lymph Node	(2)	(1)	(4)	(1)
Pancreatic, Sarcoma, Metastatic, Lymph Node, Mesenteric			1 (25%)	
Lymph Node, Bronchial	(32)	(36)	(36)	(35)
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (3%)			
Plasma Cell Tumor Malignant, Metastatic, Uncertain Primary Site	1 (3%)			
Lymph Node, Mandibular	(28)	(38)	(30)	(25)
Lymph Node, Mesenteric	(48)	(49)	(49)	(50)
Plasma Cell Tumor Malignant, Metastatic, Uncertain Primary Site	1 (2%)			
Sarcoma, Metastatic, Mesentery			1 (2%)	
Lymph Node, Mediastinal	(39)	(39)	(43)	(36)
Carcinoma, Metastatic, Intestine Small, Jejunum	1 (3%)			
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (3%)			
Plasma Cell Tumor Malignant, Metastatic, Uncertain Primary Site	1 (3%)			
Spleen	(48)	(48)	(50)	(50)
Hemangiosarcoma	2 (4%)	1 (2%)	1 (2%)	
Plasma Cell Tumor Malignant, Metastatic, Uncertain Primary Site	1 (2%)			
Thymus	(40)	(41)	(39)	(40)
Plasma Cell Tumor Malignant, Metastatic, Uncertain Primary Site	1 (3%)			
INTEGUMENTARY SYSTEM				
Skin	(49)	(50)	(50)	(50)
Subcutaneous Tissue, Fibrosarcoma		1 (2%)		
Subcutaneous Tissue, Fibrous Histiocytoma		2 (4%)	2 (4%)	
Subcutaneous Tissue, Hemangioma			1 (2%)	
Subcutaneous Tissue, Hemangiosarcoma			1 (2%)	
Subcutaneous Tissue, Histiocytic Sarcoma		1 (2%)		
Subcutaneous Tissue, Lipoma	1 (2%)			
Subcutaneous Tissue, Sarcoma		1 (2%)		

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	13 (26%)	7 (14%)		7 (14%)
Alveolar/Bronchiolar Carcinoma	6 (12%)	3 (6%)		4 (8%)
Alveolar/Bronchiolar Carcinoma, Multiple			1 (2%)	
Carcinoma, Metastatic, Harderian Gland				1 (2%)
Carcinoma, Metastatic, Intestine Small, Jejunum	1 (2%)			
Hepatoblastoma, Metastatic, Liver			1 (2%)	
Hepatocellular Carcinoma, Metastatic, Liver	3 (6%)	2 (4%)	5 (10%)	3 (6%)
Histiocytic Sarcoma		1 (2%)		
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Plasma Cell Tumor Malignant, Metastatic, Uncertain Primary Site	1 (2%)			
Sarcoma, Metastatic, Mesentery			1 (2%)	
Sarcoma, Metastatic, Skin		1 (2%)		
Bronchiole, Adenoma		1 (2%)		
Pleura	(1)		(1)	
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (100%)			
SPECIAL SENSES SYSTEM				
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	6 (12%)	4 (8%)	3 (6%)	4 (8%)
Carcinoma	1 (2%)	1 (2%)		2 (4%)
Bilateral, Adenoma			1 (2%)	

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
URINARY SYSTEM				
Kidney	(50)	(49)	(50)	(50)
Carcinoma, Metastatic, Intestine Small, Jejunum	1 (2%)			
Histiocytic Sarcoma		1 (2%)		
Osteosarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Plasma Cell Tumor Malignant, Metastatic, Uncertain Primary Site	1 (2%)			
Renal Tubule, Adenoma	1 (2%)			
Renal Tubule, Carcinoma	1 (2%)			
Urinary Bladder	(48)	(48)	(49)	(50)
Transitional Epithelium, Papilloma	1 (2%)			
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)		
Lymphoma Malignant	3 (6%)	1 (2%)	6 (12%)	3 (6%)

* Number of animals with any tissue examined microscopically

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
TUMOR SUMMARY				
Total Animals with Primary Neoplasms (b)	40	38	41	43
Total Primary Neoplasms	75	65	70	81
Total Animals with Benign Neoplasms	30	28	30	39
Total Benign Neoplasms	49	39	39	54
Total Animals with Malignant Neoplasms	20	20	26	18
Total Malignant Neoplasms	26	26	31	27
Total Animals with Metastatic Neoplasms	6	3	7	4
Total Metastatic Neoplasm	33	3	17	4
Total Animals with Malignant Neoplasms Uncertain Primary Site	2			
Total Animals with Neoplasms Uncertain-Benign or Malignant				
Total Uncertain Neoplasms				

a Number of animals examined microscopically at site and number of animals with lesion
b Primary tumors: all tumors except metastatic tumors

---------- END OF REPORT ----------

FINAL/MICE

REASONS FOR REMOVAL: ALL

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS: INCLUDE ALL

NTP
LAB: Battelle Northwest
EXPERIMENT: 90004 TEST: 06
TEST TYPE: CHRONIC
CONT: NO1-ES-55392
PATHOLOGIST: MISSING
Mice(B6C3F1)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

CAGES FROM 0000 TO LAST CAGE
ROUTE: RESPIRATORY EXPOSURE WHOLE BODY

REPORT: PEIRPT08
DATE: 01/02/02
TIME: 09:22:38

NTP C#: C90004
CAS: 57018-52-7

FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED. IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.

Adrenal Cortex
Adrenal Medulla
Bone Marrow
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Ovary
Pituitary Gland
Prostate
Spleen
Testes
Thyroid Gland
Urinary Bladder

NTP
LAB: Battelle Northwest
EXPERIMENT: 90004 TEST: 06
TEST TYPE: CHRONIC
CONT: NO1-ES-55392
PATHOLOGIST: MISSING

STATISTICAL ANALYSIS OF PRIMARY TUMORS
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

CAGES FROM 0000 TO LAST CAGE
ROUTE: RESPIRATORY EXPOSURE WHOLE BODY

REPORT: PEIRPT08
DATE: 01/02/02
TIME: 09:22:38

NTP C#: C90004
CAS: 57018-52-7

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Male Mice

Organ	Morphology
Liver	Hepatoblastoma
	Hepatocellular Adenoma
	Hepatocellular Carcinoma or Hepatocellular Adenoma
	Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma
Lung	Alveolar/Bronchiolar Adenoma
	Alveolar/Bronchiolar Carcinoma
	Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma
All Organs	Benign Tumors

Female Mice

Organ	Morphology
Liver	Hepatoblastoma
	Hepatocellular Adenoma
	Hepatocellular Carcinoma or Hepatoblastoma
	Hepatocellular Carcinoma or Hepatocellular Adenoma
	Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma
Skin	Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma
	Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma
	Sarcoma
All Organs	Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type
	Benign Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Adrenal Cortex Adenoma								
TUMOR RATES								
OVERALL (a)	1/48 (2%)	1/49 (2%)	1/50 (2%)	4/50 (8%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
POLY-3 RATE (b)	1/44.56	1/44.95	1/45.18	4/44.78	0/46.74	0/46.36	0/48.03	0/45.05
POLY-3 PERCENT (g)	2.2%	2.2%	2.2%	8.9%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	1/35 (3%)	1/40 (3%)	1/40 (3%)	3/37 (8%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	711	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.053	P=0.732N	P=0.732N	P=0.195	(e)	(e)	(e)	(e)
POLY 3	P=0.057	P=0.759N	P=0.758N	P=0.180	(e)	(e)	(e)	(e)
POLY 1.5	P=0.059	P=0.760N	P=0.755N	P=0.185	(e)	(e)	(e)	(e)
POLY 6	P=0.054	P=0.756N	P=0.759N	P=0.175	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.050	P=0.732N	P=0.732N	P=0.175	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.061	P=0.747N	P=0.742N	P=0.194	(e)	(e)	(e)	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Adrenal Cortex Carcinoma								
TUMOR RATES								
OVERALL (a)	0/48 (0%)	2/49 (4%)	0/50 (0%)	0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
POLY-3 RATE (b)	0/44.56	2/44.95	0/45.18	0/44.71	1/47.12	0/46.36	0/48.03	0/45.05
POLY-3 PERCENT (g)	0.0%	4.5%	0.0%	0.0%	2.1%	0.0%	0.0%	0.0%
TERMINAL (d)	0/35 (0%)	2/40 (5%)	0/40 (0%)	0/37 (0%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	---	729 (T)	---	---	624	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.392N	P=0.268	(e)	(e)	P=0.558N	P=0.513N	P=0.500N	P=0.517N
POLY 3	P=0.389N	P=0.239	(e)	(e)	P=0.548N	P=0.503N	P=0.496N	P=0.509N
POLY 1.5	P=0.389N	P=0.238	(e)	(e)	P=0.550N	P=0.500N	P=0.496N	P=0.507N
POLY 6	P=0.389N	P=0.242	(e)	(e)	P=0.546N	P=0.507N	P=0.496N	P=0.510N
LOGISTIC REGRESSION	(e)	P=0.268	(e)	(e)	P=0.406N	P=0.340N	P=0.574N	P=0.374N
COCH-ARM / FISHERS	P=0.384N	P=0.253	(e)	(e)	P=0.553N	P=0.495N	P=0.495N	P=0.505N

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Harderian Gland Adenoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	6/50 (12%)	4/50 (8%)	4/50 (8%)	4/50 (8%)	3/50 (6%)	4/50 (8%)	5/50 (10%)	4/50 (8%)
POLY-3 RATE (b)	6/46.18	4/45.45	4/45.18	4/45.06	3/47.55	4/46.71	5/48.81	4/45.40
POLY-3 PERCENT (g)	13.0%	8.8%	8.9%	8.9%	6.3%	8.6%	10.2%	8.8%
TERMINAL (d)	5/35 (14%)	3/40 (8%)	4/40 (10%)	3/37 (8%)	3/39 (8%)	2/36 (6%)	2/42 (5%)	4/39 (10%)
FIRST INCIDENCE	671	663	729 (T)	632	731 (T)	643	600	731 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.445N	P=0.307N	P=0.297N	P=0.348N	P=0.537	P=0.462	P=0.393	P=0.500
POLY 3	P=0.440N	P=0.379N	P=0.383N	P=0.385N	P=0.501	P=0.490	P=0.371	P=0.475
POLY 1.5	P=0.433N	P=0.384N	P=0.378N	P=0.379N	P=0.505	P=0.494	P=0.365	P=0.479
POLY 6	P=0.449N	P=0.368N	P=0.384N	P=0.388N	P=0.503	P=0.486	P=0.382	P=0.475
LOGISTIC REGRESSION	P=0.447N	P=0.377N	P=0.369N	P=0.385N	P=0.529	P=0.490	P=0.331	P=0.500
COCH-ARM / FISHERS	P=0.431N	P=0.370N	P=0.370N	P=0.370N	P=0.533	P=0.500	P=0.357	P=0.500

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Harderian Gland Carcinoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.96	1/45.21	0/45.18	2/44.78	0/47.55	2/46.83	0/48.03	2/45.40
POLY-3 PERCENT (g)	2.2%	2.2%	0.0%	4.5%	0.0%	4.3%	0.0%	4.4%
TERMINAL (d)	1/35 (3%)	1/40 (3%)	0/40 (0%)	1/37 (3%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	2/39 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	---	711	---	630	---	731 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.310	P=0.732N	P=0.473N	P=0.513	P=0.290	P=0.230	(e)	P=0.238
POLY 3	P=0.313	P=0.757	P=0.503N	P=0.491	P=0.276	P=0.234	(e)	P=0.227
POLY 1.5	P=0.316	P=0.756	P=0.502N	P=0.494	P=0.278	P=0.235	(e)	P=0.229
POLY 6	P=0.310	P=0.761N	P=0.503N	P=0.489	P=0.276	P=0.233	(e)	P=0.227
LOGISTIC REGRESSION	P=0.304	P=0.732N	(e)	P=0.490	P=0.305	P=0.299	(e)	P=0.238
COCH-ARM / FISHERS	P=0.317	P=0.753N	P=0.500N	P=0.500	P=0.290	P=0.247	(e)	P=0.247

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Harderian Gland Carcinoma or Adenoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	7/50 (14%)	5/50 (10%)	4/50 (8%)	6/50 (12%)	3/50 (6%)	6/50 (12%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	7/46.18	5/45.45	4/45.18	6/45.13	3/47.55	6/47.17	5/48.81	5/45.40
POLY-3 PERCENT (g)	15.2%	11.0%	8.9%	13.3%	6.3%	12.7%	10.2%	11.0%
TERMINAL (d)	6/35 (17%)	4/40 (10%)	4/40 (10%)	4/37 (11%)	3/39 (8%)	2/36 (6%)	2/42 (5%)	5/39 (13%)
FIRST INCIDENCE	671	663	729 (T)	632	731 (T)	630	600	731 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.548	P=0.306N	P=0.196N	P=0.472N	P=0.500	P=0.219	P=0.393	P=0.355
POLY 3	P=0.554	P=0.390N	P=0.273N	P=0.518N	P=0.459	P=0.238	P=0.371	P=0.332
POLY 1.5	P=0.561	P=0.395N	P=0.269N	P=0.511N	P=0.465	P=0.240	P=0.365	P=0.336
POLY 6	P=0.545	P=0.378N	P=0.274N	P=0.521N	P=0.458	P=0.238	P=0.382	P=0.331
LOGISTIC REGRESSION	P=0.542	P=0.385N	P=0.257N	P=0.523N	P=0.506	P=0.260	P=0.331	P=0.355
COCH-ARM / FISHERS	P=0.563	P=0.380N	P=0.262N	P=0.500N	P=0.496	P=0.243	P=0.357	P=0.357

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Intestine Small: Duodenum Polyp Adenomatous								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.96	2/45.21	1/45.18	0/44.71	0/47.55	0/46.36	0/48.03	0/45.40
POLY-3 PERCENT (g)	0.0%	4.4%	2.2%	0.0%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	0/35 (0%)	2/40 (5%)	1/40 (3%)	0/37 (0%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.369N	P=0.268	P=0.527	(e)	(e)	(e)	(e)	(e)
POLY 3	P=0.374N	P=0.234	P=0.497	(e)	(e)	(e)	(e)	(e)
POLY 1.5	P=0.372N	P=0.232	P=0.498	(e)	(e)	(e)	(e)	(e)
POLY 6	P=0.375N	P=0.237	P=0.497	(e)	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	P=0.268	P=0.527	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.366N	P=0.247	P=0.500	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Intestine Small: Jejunum Carcinoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/46.03	1/45.21	1/45.18	1/44.71	0/47.55	0/46.36	0/48.03	1/45.40
POLY-3 PERCENT (g)	4.4%	2.2%	2.2%	2.2%	0.0%	0.0%	0.0%	2.2%
TERMINAL (d)	1/35 (3%)	1/40 (3%)	1/40 (3%)	1/37 (3%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	1/39 (3%)
FIRST INCIDENCE	711	729 (T)	729 (T)	729 (T)	---	---	---	731 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.529N	P=0.460N	P=0.463N	P=0.487N	P=0.230	(e)	(e)	P=0.500
POLY 3	P=0.526N	P=0.506N	P=0.507N	P=0.510N	P=0.223	(e)	(e)	P=0.491
POLY 1.5	P=0.522N	P=0.508N	P=0.504N	P=0.506N	P=0.223	(e)	(e)	P=0.492
POLY 6	P=0.531N	P=0.501N	P=0.506N	P=0.513N	P=0.224	(e)	(e)	P=0.491
LOGISTIC REGRESSION	P=0.536N	P=0.495N	P=0.500N	P=0.510N	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.521N	P=0.500N	P=0.500N	P=0.500N	P=0.228	(e)	(e)	P=0.500

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Intestine Small: Site Unspecified Carcinoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/46.03	1/45.21	2/45.18	1/44.71	1/47.74	0/46.36	0/48.03	1/45.40
POLY-3 PERCENT (g)	4.4%	2.2%	4.4%	2.2%	2.1%	0.0%	0.0%	2.2%
TERMINAL (d)	1/35 (3%)	1/40 (3%)	2/40 (5%)	1/37 (3%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	1/39 (3%)
FIRST INCIDENCE	711	729 (T)	729 (T)	729 (T)	680	---	---	731 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.495N	P=0.460N	P=0.652N	P=0.487N	P=0.520	P=0.513N	P=0.509N	P=0.753
POLY 3	P=0.494N	P=0.506N	P=0.687	P=0.510N	P=0.516	P=0.506N	P=0.499N	P=0.749
POLY 1.5	P=0.489N	P=0.508N	P=0.690	P=0.506N	P=0.516	P=0.503N	P=0.499N	P=0.751
POLY 6	P=0.501N	P=0.501N	P=0.688	P=0.513N	P=0.519	P=0.509N	P=0.498N	P=0.749
LOGISTIC REGRESSION	P=0.503N	P=0.495N	P=0.693N	P=0.510N	P=0.528	P=0.455N	P=0.523N	P=0.765N
COCH-ARM / FISHERS	P=0.487N	P=0.500N	P=0.691N	P=0.500N	P=0.522	P=0.500N	P=0.500N	P=0.753N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Intestine Small: Site Unspecified Polyp Adenomatous								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.96	2/45.21	2/45.18	1/44.71	0/47.55	0/46.36	0/48.03	0/45.40
POLY-3 PERCENT (g)	2.2%	4.4%	4.4%	2.2%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	1/35 (3%)	2/40 (5%)	2/40 (5%)	1/37 (3%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.519N	P=0.547	P=0.547	P=0.749N	(e)	(e)	(e)	(e)
POLY 3	P=0.522N	P=0.494	P=0.494	P=0.755	(e)	(e)	(e)	(e)
POLY 1.5	P=0.517N	P=0.492	P=0.496	P=0.757	(e)	(e)	(e)	(e)
POLY 6	P=0.527N	P=0.500	P=0.495	P=0.753	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.519N	P=0.547	P=0.547	P=0.749N	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.513N	P=0.500	P=0.500	P=0.753N	(e)	(e)	(e)	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Islets, Pancreatic Adenoma								
TUMOR RATES								
OVERALL (a)	2/48 (4%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
POLY-3 RATE (b)	2/44.56	0/44.95	0/45.18	0/44.71	1/46.74	0/46.36	0/48.03	0/45.05
POLY-3 PERCENT (g)	4.5%	0.0%	0.0%	0.0%	2.1%	0.0%	0.0%	0.0%
TERMINAL (d)	2/35 (6%)	0/40 (0%)	0/40 (0%)	0/37 (0%)	1/39 (3%)	0/36 (0%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	729 (T)	---	---	---	731 (T)	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.309N	P=0.209N	P=0.209N	P=0.226N	P=0.543N	P=0.516N	P=0.485N	P=0.500N
POLY 3	P=0.300N	P=0.235N	P=0.234N	P=0.236N	P=0.550N	P=0.502N	P=0.495N	P=0.507N
POLY 1.5	P=0.299N	P=0.237N	P=0.232N	P=0.233N	P=0.551N	P=0.499N	P=0.495N	P=0.507N
POLY 6	P=0.304N	P=0.232N	P=0.235N	P=0.240N	P=0.548N	P=0.505N	P=0.494N	P=0.507N
LOGISTIC REGRESSION	P=0.309N	(e)	(e)	(e)	P=0.543N	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.303N	P=0.242N	P=0.237N	P=0.237N	P=0.553N	P=0.495N	P=0.495N	P=0.505N

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Kidney: Renal Tubule Carcinoma or Adenoma								
TUMOR RATES								
OVERALL (a)	2/50 (4%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
POLY-3 RATE (b)	2/45.96	0/44.95	0/45.18	0/44.71	0/46.74	0/46.36	0/48.03	0/45.05
POLY-3 PERCENT (g)	4.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	2/35 (6%)	0/40 (0%)	0/40 (0%)	0/37 (0%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	729 (T)	---	---	---	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.309N	P=0.209N	P=0.209N	P=0.226N	(e)	(e)	(e)	(e)
POLY 3	P=0.306N	P=0.242N	P=0.241N	P=0.243N	(e)	(e)	(e)	(e)
POLY 1.5	P=0.304N	P=0.245N	P=0.240N	P=0.241N	(e)	(e)	(e)	(e)
POLY 6	P=0.311N	P=0.237N	P=0.240N	P=0.245N	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.309N	(e)	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.307N	P=0.253N	P=0.247N	P=0.247N	(e)	(e)	(e)	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Liver Hemangiosarcoma								
TUMOR RATES								
OVERALL (a)	2/50 (4%)	0/49 (0%)	1/50 (2%)	1/50 (2%)	0/49 (0%)	2/50 (4%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	2/46.27	0/44.95	1/45.60	1/44.78	0/46.74	2/46.36	0/48.03	0/45.40
POLY-3 PERCENT (g)	4.3%	0.0%	2.2%	2.2%	0.0%	4.3%	0.0%	0.0%
TERMINAL (d)	0/35 (0%)	0/40 (0%)	0/40 (0%)	0/37 (0%)	0/39 (0%)	2/36 (6%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	668	---	606	711	---	731 (T)	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.671N	P=0.239N	P=0.518N	P=0.514N	P=0.385N	P=0.221	(e)	(e)
POLY 3	P=0.656N	P=0.244N	P=0.505N	P=0.511N	P=0.401N	P=0.235	(e)	(e)
POLY 1.5	P=0.651N	P=0.246N	P=0.503N	P=0.507N	P=0.398N	P=0.238	(e)	(e)
POLY 6	P=0.663N	P=0.240N	P=0.504N	P=0.515N	P=0.405N	P=0.232	(e)	(e)
LOGISTIC REGRESSION	P=0.653N	P=0.238N	P=0.497N	P=0.498N	(e)	P=0.221	(e)	(e)
COCH-ARM / FISHERS	P=0.651N	P=0.253N	P=0.500N	P=0.500N	P=0.392N	P=0.253	(e)	(e)

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Liver Hepatoblastoma								
TUMOR RATES								
OVERALL (a)	0/50 (0%)	0/49 (0%)	1/50 (2%)	5/50 (10%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/45.96	0/44.95	1/45.18	5/44.71	0/46.74	0/46.36	0/48.03	2/45.40
POLY-3 PERCENT (g)	0.0%	0.0%	2.2%	11.2%	0.0%	0.0%	0.0%	4.4%
TERMINAL (d)	0/35 (0%)	0/40 (0%)	1/40 (3%)	5/37 (14%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	2/39 (5%)
FIRST INCIDENCE	---	---	729 (T)	729 (T)	---	---	---	731 (T)
STATISTICAL TESTS								
LIFE TABLE	P<0.001 **	(e)	P=0.527	P=0.038 *	P=0.043 *	(e)	(e)	P=0.238
POLY 3	P<0.001 **	(e)	P=0.497	P=0.028 *	P=0.039 *	(e)	(e)	P=0.231
POLY 1.5	P<0.001 **	(e)	P=0.498	P=0.029 *	P=0.039 *	(e)	(e)	P=0.233
POLY 6	P<0.001 **	(e)	P=0.497	P=0.027 *	P=0.039 *	(e)	(e)	P=0.230
LOGISTIC REGRESSION	(e)	(e)	P=0.527	P=0.038 *	(e)	(e)	(e)	P=0.238
COCH-ARM / FISHERS	P<0.001 **	(e)	P=0.500	P=0.028 *	P=0.041 *	(e)	(e)	P=0.247

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Liver Hepatocellular Adenoma								
TUMOR RATES								
OVERALL (a)	18/50 (36%)	23/49 (47%)	26/50 (52%)	36/50 (72%)	14/49 (29%)	8/50 (16%)	10/50 (20%)	37/49 (76%)
POLY-3 RATE (b)	18/46.93	23/45.11	26/45.60	36/46.93	14/46.96	8/46.80	10/48.03	37/46.66
POLY-3 PERCENT (g)	38.4%	51.0%	57.0%	76.7%	29.8%	17.1%	20.8%	79.3%
TERMINAL (d)	13/35 (37%)	21/40 (53%)	24/40 (60%)	29/37 (78%)	12/39 (31%)	7/36 (19%)	10/42 (24%)	32/39 (82%)
FIRST INCIDENCE	622	705	642	527	680	602	731 (T)	519
STATISTICAL TESTS								
LIFE TABLE	P<0.001 **	P=0.376	P=0.187	P=0.002 **	P<0.001 **	P=0.158N	P=0.185N	P<0.001 **
POLY 3	P<0.001 **	P=0.154	P=0.052	P<0.001 **	P<0.001 **	P=0.112N	P=0.220N	P<0.001 **
POLY 1.5	P<0.001 **	P=0.154	P=0.062	P<0.001 **	P<0.001 **	P=0.108N	P=0.222N	P<0.001 **
POLY 6	P<0.001 **	P=0.159	P=0.045 *	P<0.001 **	P<0.001 **	P=0.118N	P=0.218N	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	P=0.196	P=0.059	P<0.001 **	P<0.001 **	P=0.123N	P=0.200N	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	P=0.184	P=0.079	P<0.001 **	P<0.001 **	P=0.103N	P=0.224N	P<0.001 **

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Liver								
Hepatocellular Carcinoma								
TUMOR RATES								
OVERALL (a)	9/50 (18%)	8/49 (16%)	13/50 (26%)	11/50 (22%)	4/49 (8%)	8/50 (16%)	7/50 (14%)	10/49 (20%)
POLY-3 RATE (b)	9/46.90	8/45.11	13/48.04	11/46.52	4/47.39	8/47.98	7/48.48	10/47.16
POLY-3 PERCENT (g)	19.2%	17.7%	27.1%	23.7%	8.4%	16.7%	14.4%	21.2%
TERMINAL (d)	5/35 (14%)	6/40 (15%)	7/40 (18%)	5/37 (14%)	1/39 (3%)	3/36 (8%)	6/42 (14%)	6/39 (15%)
FIRST INCIDENCE	630	705	463	560	624	586	600	440
STATISTICAL TESTS								
LIFE TABLE	P=0.329	P=0.417N	P=0.305	P=0.418	P=0.125	P=0.167	P=0.300	P=0.081
POLY 3	P=0.348	P=0.535N	P=0.253	P=0.393	P=0.109	P=0.183	P=0.275	P=0.071
POLY 1.5	P=0.354	P=0.538N	P=0.247	P=0.396	P=0.110	P=0.185	P=0.275	P=0.072
POLY 6	P=0.346	P=0.527N	P=0.266	P=0.396	P=0.111	P=0.181	P=0.274	P=0.071
LOGISTIC REGRESSION	P=0.355	P=0.525N	P=0.254	P=0.414	P=0.190	P=0.296	P=0.249	P=0.130
COCH-ARM / FISHERS	P=0.352	P=0.518N	P=0.235	P=0.402	P=0.111	P=0.188	P=0.274	P=0.074

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Liver								
Hepatocellular Carcinoma or Hepatoblastoma								
TUMOR RATES								
OVERALL (a)	9/50 (18%)	8/49 (16%)	13/50 (26%)	12/50 (24%)	4/49 (8%)	8/50 (16%)	7/50 (14%)	12/49 (24%)
POLY-3 RATE (b)	9/46.90	8/45.11	13/48.04	12/46.52	4/47.39	8/47.98	7/48.48	12/47.16
POLY-3 PERCENT (g)	19.2%	17.7%	27.1%	25.8%	8.4%	16.7%	14.4%	25.4%
TERMINAL (d)	5/35 (14%)	6/40 (15%)	7/40 (18%)	6/37 (16%)	1/39 (3%)	3/36 (8%)	6/42 (14%)	8/39 (21%)
FIRST INCIDENCE	630	705	463	560	624	586	600	440
STATISTICAL TESTS								
LIFE TABLE	P=0.237	P=0.417N	P=0.305	P=0.336	P=0.041 *	P=0.167	P=0.300	P=0.033 *
POLY 3	P=0.248	P=0.535N	P=0.253	P=0.303	P=0.031 *	P=0.183	P=0.275	P=0.025 *
POLY 1.5	P=0.253	P=0.538N	P=0.247	P=0.306	P=0.031 *	P=0.185	P=0.275	P=0.025 *
POLY 6	P=0.246	P=0.527N	P=0.266	P=0.306	P=0.031 *	P=0.181	P=0.274	P=0.025 *
LOGISTIC REGRESSION	P=0.254	P=0.525N	P=0.254	P=0.321	P=0.059	P=0.296	P=0.249	P=0.048 *
COCH-ARM / FISHERS	P=0.252	P=0.518N	P=0.235	P=0.312	P=0.032 *	P=0.188	P=0.274	P=0.027 *

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Liver Hepatocellular Carcinoma or Hepatocellular Adenoma								
TUMOR RATES								
OVERALL (a)	25/50 (50%)	26/49 (53%)	33/50 (66%)	41/50 (82%)	18/49 (37%)	14/50 (28%)	16/50 (32%)	41/49 (84%)
POLY-3 RATE (b)	25/47.87	26/45.11	33/48.04	41/48.25	18/47.61	14/47.98	16/48.48	41/47.59
POLY-3 PERCENT (g)	52.2%	57.6%	68.7%	85.0%	37.8%	29.2%	33.0%	86.2%
TERMINAL (d)	16/35 (46%)	24/40 (60%)	27/40 (68%)	31/37 (84%)	13/39 (33%)	9/36 (25%)	15/42 (36%)	34/39 (87%)
FIRST INCIDENCE	622	705	463	527	624	586	600	440
STATISTICAL TESTS								
LIFE TABLE	P<0.001 **	P=0.442N	P=0.233	P=0.009 **	P<0.001 **	P=0.354N	P=0.336N	P<0.001 **
POLY 3	P<0.001 **	P=0.375	P=0.071	P<0.001 **	P<0.001 **	P=0.249N	P=0.391N	P<0.001 **
POLY 1.5	P<0.001 **	P=0.390	P=0.075	P<0.001 **	P<0.001 **	P=0.245N	P=0.389N	P<0.001 **
POLY 6	P<0.001 **	P=0.359	P=0.068	P<0.001 **	P<0.001 **	P=0.256N	P=0.395N	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	P=0.451	P=0.074	P<0.001 **	P<0.001 **	P=0.208N	P=0.385N	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	P=0.459	P=0.078	P<0.001 **	P<0.001 **	P=0.238N	P=0.388N	P<0.001 **

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Liver Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma								
TUMOR RATES								
OVERALL (a)	25/50 (50%)	26/49 (53%)	33/50 (66%)	41/50 (82%)	18/49 (37%)	14/50 (28%)	16/50 (32%)	41/49 (84%)
POLY-3 RATE (b)	25/47.87	26/45.11	33/48.04	41/48.25	18/47.61	14/47.98	16/48.48	41/47.59
POLY-3 PERCENT (g)	52.2%	57.6%	68.7%	85.0%	37.8%	29.2%	33.0%	86.2%
TERMINAL (d)	16/35 (46%)	24/40 (60%)	27/40 (68%)	31/37 (84%)	13/39 (33%)	9/36 (25%)	15/42 (36%)	34/39 (87%)
FIRST INCIDENCE	622	705	463	527	624	586	600	440
STATISTICAL TESTS								
LIFE TABLE	P<0.001 **	P=0.442N	P=0.233	P=0.009 **	P<0.001 **	P=0.354N	P=0.336N	P<0.001 **
POLY 3	P<0.001 **	P=0.375	P=0.071	P<0.001 **	P<0.001 **	P=0.249N	P=0.391N	P<0.001 **
POLY 1.5	P<0.001 **	P=0.390	P=0.075	P<0.001 **	P<0.001 **	P=0.245N	P=0.389N	P<0.001 **
POLY 6	P<0.001 **	P=0.359	P=0.068	P<0.001 **	P<0.001 **	P=0.256N	P=0.395N	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	P=0.451	P=0.074	P<0.001 **	P<0.001 **	P=0.208N	P=0.385N	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	P=0.459	P=0.078	P<0.001 **	P<0.001 **	P=0.238N	P=0.388N	P<0.001 **

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Lung Alveolar/Bronchiolar Adenoma								
TUMOR RATES								
OVERALL (a)	13/50 (26%)	7/50 (14%)	0/50 (0%)	7/50 (14%)	2/50 (4%)	2/50 (4%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	13/46.56	7/45.37	0/45.18	7/45.47	2/47.55	2/46.72	2/48.03	0/45.40
POLY-3 PERCENT (g)	27.9%	15.4%	0.0%	15.4%	4.2%	4.3%	4.2%	0.0%
TERMINAL (d)	11/35 (31%)	5/40 (13%)	0/40 (0%)	5/37 (14%)	2/39 (5%)	1/36 (3%)	2/42 (5%)	0/39 (0%)
FIRST INCIDENCE	622	705	---	599	731 (T)	630	731 (T)	---
STATISTICAL TESTS								
LIFE TABLE	P=0.311N	P=0.067N	P<0.001N**	P=0.095N	P=0.154N	P=0.668	P=0.668N	P=0.238N
POLY 3	P=0.286N	P=0.114N	P<0.001N**	P=0.113N	P=0.167N	P=0.687	P=0.690N	P=0.248N
POLY 1.5	P=0.283N	P=0.116N	P<0.001N**	P=0.110N	P=0.166N	P=0.690	P=0.692N	P=0.246N
POLY 6	P=0.290N	P=0.108N	P<0.001N**	P=0.114N	P=0.166N	P=0.685	P=0.687N	P=0.247N
LOGISTIC REGRESSION	P=0.305N	P=0.108N	P<0.001N**	P=0.114N	P=0.161N	P=0.681N	P=0.668N	(e)
COCH-ARM / FISHERS	P=0.293N	P=0.105N	P<0.001N**	P=0.105N	P=0.161N	P=0.691N	P=0.691N	P=0.253N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Lung Alveolar/Bronchiolar Carcinoma								
TUMOR RATES								
OVERALL (a)	6/50 (12%)	3/50 (6%)	1/50 (2%)	4/50 (8%)	1/50 (2%)	3/50 (6%)	1/50 (2%)	1/49 (2%)
POLY-3 RATE (b)	6/46.41	3/45.21	1/45.18	4/44.71	1/47.55	3/46.47	1/48.03	1/45.40
POLY-3 PERCENT (g)	12.9%	6.6%	2.2%	9.0%	2.1%	6.5%	2.1%	2.2%
TERMINAL (d)	4/35 (11%)	3/40 (8%)	1/40 (3%)	4/37 (11%)	1/39 (3%)	2/36 (6%)	1/42 (2%)	1/39 (3%)
FIRST INCIDENCE	669	729 (T)	729 (T)	729 (T)	731 (T)	705	731 (T)	731 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.574N	P=0.199N	P=0.049N*	P=0.352N	P=0.427N	P=0.281	P=0.745N	P=0.762
POLY 3	P=0.569N	P=0.255N	P=0.060N	P=0.393N	P=0.454N	P=0.297	P=0.758N	P=0.750
POLY 1.5	P=0.562N	P=0.256N	P=0.059N	P=0.383N	P=0.451N	P=0.301	P=0.759N	P=0.752
POLY 6	P=0.578N	P=0.250N	P=0.061N	P=0.403N	P=0.454N	P=0.293	P=0.757N	P=0.750
LOGISTIC REGRESSION	P=0.581N	P=0.249N	P=0.060N	P=0.389N	P=0.443N	P=0.289	P=0.745N	P=0.762
COCH-ARM / FISHERS	P=0.560N	P=0.243N	P=0.056N	P=0.370N	P=0.444N	P=0.309	P=0.753N	P=0.747

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Lung Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma								
TUMOR RATES								
OVERALL (a)	17/50 (34%)	10/50 (20%)	1/50 (2%)	10/50 (20%)	3/50 (6%)	5/50 (10%)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	17/47.01	10/45.37	1/45.18	10/45.47	3/47.55	5/46.83	3/48.03	1/45.40
POLY-3 PERCENT (g)	36.2%	22.0%	2.2%	22.0%	6.3%	10.7%	6.3%	2.2%
TERMINAL (d)	13/35 (37%)	8/40 (20%)	1/40 (3%)	8/37 (22%)	3/39 (8%)	3/36 (8%)	3/42 (7%)	1/39 (3%)
FIRST INCIDENCE	622	705	729 (T)	599	731 (T)	630	731 (T)	731 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.313N	P=0.053N	P<0.001N**	P=0.081N	P=0.127N	P=0.320	P=0.629N	P=0.305N
POLY 3	P=0.284N	P=0.102N	P<0.001N**	P=0.100N	P=0.144N	P=0.348	P=0.657N	P=0.322N
POLY 1.5	P=0.280N	P=0.101N	P<0.001N**	P=0.094N	P=0.143N	P=0.352	P=0.659N	P=0.320N
POLY 6	P=0.291N	P=0.099N	P<0.001N**	P=0.106N	P=0.144N	P=0.345	P=0.654N	P=0.322N
LOGISTIC REGRESSION	P=0.308N	P=0.093N	P<0.001N**	P=0.097N	P=0.140N	P=0.352	P=0.629N	P=0.305N
COCH-ARM / FISHERS	P=0.291N	P=0.088N	P<0.001N**	P=0.088N	P=0.137N	P=0.357	P=0.661N	P=0.316N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Mesentery Hemangiosarcoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.96	2/45.21	0/45.18	0/44.71	1/47.55	0/46.36	0/48.03	0/45.40
POLY-3 PERCENT (g)	0.0%	4.4%	0.0%	0.0%	2.1%	0.0%	0.0%	0.0%
TERMINAL (d)	0/35 (0%)	2/40 (5%)	0/40 (0%)	0/37 (0%)	1/39 (3%)	0/36 (0%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	---	729 (T)	---	---	731 (T)	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.392N	P=0.268	(e)	(e)	P=0.543N	P=0.516N	P=0.485N	P=0.500N
POLY 3	P=0.395N	P=0.234	(e)	(e)	P=0.546N	P=0.505N	P=0.498N	P=0.509N
POLY 1.5	P=0.395N	P=0.232	(e)	(e)	P=0.546N	P=0.503N	P=0.499N	P=0.508N
POLY 6	P=0.394N	P=0.237	(e)	(e)	P=0.545N	P=0.508N	P=0.496N	P=0.509N
LOGISTIC REGRESSION	(e)	P=0.268	(e)	(e)	P=0.543N	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.390N	P=0.247	(e)	(e)	P=0.547N	P=0.500N	P=0.500N	P=0.500N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Ovary Cystadenoma								
TUMOR RATES								
OVERALL (a)					2/50 (4%)	1/49 (2%)	3/49 (6%)	1/48 (2%)
POLY-3 RATE (b)					2/47.55	1/45.91	3/47.03	1/45.05
POLY-3 PERCENT (g)					4.2%	2.2%	6.4%	2.2%
TERMINAL (d)					2/39 (5%)	0/36 (0%)	3/41 (7%)	1/39 (3%)
FIRST INCIDENCE					731 (T)	705	731 (T)	731 (T)
STATISTICAL TESTS								
LIFE TABLE					P=0.448N	P=0.524N	P=0.523	P=0.500N
POLY 3					P=0.475N	P=0.512N	P=0.495	P=0.519N
POLY 1.5					P=0.475N	P=0.510N	P=0.493	P=0.518N
POLY 6					P=0.471N	P=0.514N	P=0.498	P=0.517N
LOGISTIC REGRESSION					P=0.463N	P=0.515N	P=0.523	P=0.500N
COCH-ARM / FISHERS					P=0.471N	P=0.508N	P=0.490	P=0.515N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Ovary Luteoma								
TUMOR RATES								
OVERALL (a)					2/50 (4%)	0/49 (0%)	1/49 (2%)	1/48 (2%)
POLY-3 RATE (b)					2/47.55	0/45.80	1/47.03	1/45.05
POLY-3 PERCENT (g)					4.2%	0.0%	2.1%	2.2%
TERMINAL (d)					2/39 (5%)	0/36 (0%)	1/41 (2%)	1/39 (3%)
FIRST INCIDENCE					731 (T)	---	731 (T)	731 (T)
STATISTICAL TESTS								
LIFE TABLE					P=0.646N	P=0.256N	P=0.483N	P=0.500N
POLY 3					P=0.664N	P=0.246N	P=0.504N	P=0.519N
POLY 1.5					P=0.664N	P=0.244N	P=0.505N	P=0.518N
POLY 6					P=0.661N	P=0.247N	P=0.501N	P=0.517N
LOGISTIC REGRESSION					P=0.646N	(e)	P=0.483N	P=0.500N
COCH-ARM / FISHERS					P=0.664N	P=0.253N	P=0.508N	P=0.515N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma								
TUMOR RATES								
OVERALL (a)	0/43 (0%)	0/48 (0%)	0/50 (0%)	0/48 (0%)	9/48 (19%)	11/49 (22%)	12/47 (26%)	8/46 (17%)
POLY-3 RATE (b)	0/40.90	0/43.95	0/45.18	0/42.78	9/46.12	11/46.14	12/45.31	8/43.26
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	19.5%	23.8%	26.5%	18.5%
TERMINAL (d)	0/34 (0%)	0/39 (0%)	0/40 (0%)	0/36 (0%)	8/38 (21%)	8/36 (22%)	11/39 (28%)	6/38 (16%)
FIRST INCIDENCE	---	---	---	---	680	669	656	722
STATISTICAL TESTS								
LIFE TABLE	(e)	(e)	(e)	(e)	P=0.306N	P=0.353	P=0.332	P=0.501N
POLY 3	(e)	(e)	(e)	(e)	P=0.386N	P=0.401	P=0.294	P=0.558N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.383N	P=0.410	P=0.293	P=0.552N
POLY 6	(e)	(e)	(e)	(e)	P=0.380N	P=0.392	P=0.296	P=0.557N
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.366N	P=0.384	P=0.294	P=0.545N
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	P=0.369N	P=0.421	P=0.292	P=0.539N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	4/50 (8%)	2/50 (4%)	0/50 (0%)	1/50 (2%)	8/50 (16%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/45.96	4/45.57	2/45.18	0/44.71	1/47.83	8/47.26	1/48.03	2/45.55
POLY-3 PERCENT (g)	0.0%	8.8%	4.4%	0.0%	2.1%	16.9%	2.1%	4.4%
TERMINAL (d)	0/35 (0%)	3/40 (8%)	2/40 (5%)	0/37 (0%)	0/39 (0%)	5/36 (14%)	1/42 (2%)	1/39 (3%)
FIRST INCIDENCE	---	627	729 (T)	---	653	533	731 (T)	694
STATISTICAL TESTS								
LIFE TABLE	P=0.194N	P=0.077	P=0.268	(e)	P=0.274N	P=0.017 *	P=0.750N	P=0.492
POLY 3	P=0.196N	P=0.059	P=0.233	(e)	P=0.291N	P=0.015 *	P=0.760N	P=0.483
POLY 1.5	P=0.193N	P=0.058	P=0.235	(e)	P=0.286N	P=0.015 *	P=0.760N	P=0.486
POLY 6	P=0.197N	P=0.062	P=0.234	(e)	P=0.292N	P=0.014 *	P=0.759N	P=0.483
LOGISTIC REGRESSION	P=0.193N	P=0.061	P=0.268	(e)	P=0.240N	P=0.025 *	P=0.748	P=0.515
COCH-ARM / FISHERS	P=0.190N	P=0.059	P=0.247	(e)	P=0.272N	P=0.015 *	P=0.753N	P=0.500

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin								
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	4/50 (8%)	2/50 (4%)	0/50 (0%)	1/50 (2%)	8/50 (16%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/45.96	4/45.57	2/45.18	0/44.71	1/47.83	8/47.26	1/48.03	2/45.55
POLY-3 PERCENT (g)	0.0%	8.8%	4.4%	0.0%	2.1%	16.9%	2.1%	4.4%
TERMINAL (d)	0/35 (0%)	3/40 (8%)	2/40 (5%)	0/37 (0%)	0/39 (0%)	5/36 (14%)	1/42 (2%)	1/39 (3%)
FIRST INCIDENCE	---	627	729 (T)	---	653	533	731 (T)	694
STATISTICAL TESTS								
LIFE TABLE	P=0.194N	P=0.077	P=0.268	(e)	P=0.274N	P=0.017 *	P=0.750N	P=0.492
POLY 3	P=0.196N	P=0.059	P=0.233	(e)	P=0.291N	P=0.015 *	P=0.760N	P=0.483
POLY 1.5	P=0.193N	P=0.058	P=0.235	(e)	P=0.286N	P=0.015 *	P=0.760N	P=0.486
POLY 6	P=0.197N	P=0.062	P=0.234	(e)	P=0.292N	P=0.014 *	P=0.759N	P=0.483
LOGISTIC REGRESSION	P=0.193N	P=0.061	P=0.268	(e)	P=0.240N	P=0.025 *	P=0.748	P=0.515
COCH-ARM / FISHERS	P=0.190N	P=0.059	P=0.247	(e)	P=0.272N	P=0.015 *	P=0.753N	P=0.500

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin								
Fibrous Histiocytoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.96	2/45.21	2/45.18	0/44.71	0/47.55	0/46.36	0/48.03	0/45.40
POLY-3 PERCENT (g)	0.0%	4.4%	4.4%	0.0%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	0/35 (0%)	2/40 (5%)	2/40 (5%)	0/37 (0%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.349N	P=0.268	P=0.268	(e)	(e)	(e)	(e)	(e)
POLY 3	P=0.355N	P=0.234	P=0.233	(e)	(e)	(e)	(e)	(e)
POLY 1.5	P=0.351N	P=0.232	P=0.235	(e)	(e)	(e)	(e)	(e)
POLY 6	P=0.358N	P=0.237	P=0.234	(e)	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	P=0.268	P=0.268	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.346N	P=0.247	P=0.247	(e)	(e)	(e)	(e)	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Skin								
Sarcoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	8/50 (16%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/45.96	1/45.57	0/45.18	0/44.71	1/47.83	8/47.26	1/48.03	2/45.55
POLY-3 PERCENT (g)	0.0%	2.2%	0.0%	0.0%	2.1%	16.9%	2.1%	4.4%
TERMINAL (d)	0/35 (0%)	0/40 (0%)	0/40 (0%)	0/37 (0%)	0/39 (0%)	5/36 (14%)	1/42 (2%)	1/39 (3%)
FIRST INCIDENCE	---	627	---	---	653	533	731 (T)	694
STATISTICAL TESTS								
LIFE TABLE	P=0.615N	P=0.491	(e)	(e)	P=0.274N	P=0.017 *	P=0.750N	P=0.492
POLY 3	P=0.610N	P=0.498	(e)	(e)	P=0.291N	P=0.015 *	P=0.760N	P=0.483
POLY 1.5	P=0.611N	P=0.496	(e)	(e)	P=0.286N	P=0.015 *	P=0.760N	P=0.486
POLY 6	P=0.608N	P=0.503	(e)	(e)	P=0.292N	P=0.014 *	P=0.759N	P=0.483
LOGISTIC REGRESSION	P=0.620N	P=0.529	(e)	(e)	P=0.240N	P=0.025 *	P=0.748	P=0.515
COCH-ARM / FISHERS	P=0.608N	P=0.500	(e)	(e)	P=0.272N	P=0.015 *	P=0.753N	P=0.500

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Spleen								
Hemangiosarcoma								
TUMOR RATES								
OVERALL (a)	2/48 (4%)	1/48 (2%)	1/50 (2%)	0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/48 (0%)
POLY-3 RATE (b)	2/44.79	1/44.30	1/45.18	0/44.71	0/46.74	1/46.37	0/48.03	0/45.05
POLY-3 PERCENT (g)	4.5%	2.3%	2.2%	0.0%	0.0%	2.2%	0.0%	0.0%
TERMINAL (d)	1/35 (3%)	1/40 (3%)	1/40 (3%)	0/37 (0%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	668	729 (T)	729 (T)	---	---	730	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.220N	P=0.475N	P=0.477N	P=0.244N	P=0.607N	P=0.489	(e)	(e)
POLY 3	P=0.213N	P=0.504N	P=0.497N	P=0.237N	P=0.620N	P=0.498	(e)	(e)
POLY 1.5	P=0.209N	P=0.506N	P=0.492N	P=0.234N	P=0.617N	P=0.501	(e)	(e)
POLY 6	P=0.218N	P=0.499N	P=0.501N	P=0.242N	P=0.622N	P=0.495	(e)	(e)
LOGISTIC REGRESSION	P=0.211N	P=0.503N	P=0.490N	P=0.227N	P=0.607N	P=0.490	(e)	(e)
COCH-ARM / FISHERS	P=0.206N	P=0.500N	P=0.485N	P=0.237N	P=0.614N	P=0.505	(e)	(e)

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Testes Adenoma								
TUMOR RATES								
OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)				
POLY-3 RATE (b)	2/46.18	0/45.21	2/45.18	0/44.71				
POLY-3 PERCENT (g)	4.3%	0.0%	4.4%	0.0%				
TERMINAL (d)	1/35 (3%)	0/40 (0%)	2/40 (5%)	0/37 (0%)				
FIRST INCIDENCE	669	---	729 (T)	---				
STATISTICAL TESTS								
LIFE TABLE	P=0.296N	P=0.228N	P=0.662N	P=0.241N				
POLY 3	P=0.293N	P=0.242N	P=0.686	P=0.244N				
POLY 1.5	P=0.289N	P=0.243N	P=0.689	P=0.242N				
POLY 6	P=0.300N	P=0.239N	P=0.685	P=0.247N				
LOGISTIC REGRESSION	P=0.294N	P=0.238N	P=0.690	P=0.237N				
COCH-ARM / FISHERS	P=0.290N	P=0.247N	P=0.691N	P=0.247N				

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Thyroid Gland: Follicular Cell Carcinoma or Adenoma								
TUMOR RATES								
OVERALL (a)	1/48 (2%)	0/48 (0%)	2/49 (4%)	0/49 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
POLY-3 RATE (b)	1/44.56	0/44.31	2/44.18	0/43.71	0/46.83	0/46.36	0/48.03	0/45.05
POLY-3 PERCENT (g)	2.2%	0.0%	4.5%	0.0%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	1/35 (3%)	0/40 (0%)	2/39 (5%)	0/36 (0%)	0/39 (0%)	0/36 (0%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---	---	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.447N	P=0.473N	P=0.538	P=0.494N	(e)	(e)	(e)	(e)
POLY 3	P=0.444N	P=0.501N	P=0.497	P=0.504N	(e)	(e)	(e)	(e)
POLY 1.5	P=0.436N	P=0.503N	P=0.501	P=0.501N	(e)	(e)	(e)	(e)
POLY 6	P=0.453N	P=0.498N	P=0.494	P=0.507N	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.447N	(e)	P=0.538	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.431N	P=0.500N	P=0.508	P=0.495N	(e)	(e)	(e)	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Uterus Hemangiosarcoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)					0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)					0/47.55	0/46.36	2/48.03	0/45.40
POLY-3 PERCENT (g)					0.0%	0.0%	4.2%	0.0%
TERMINAL (d)					0/39 (0%)	0/36 (0%)	2/42 (5%)	0/39 (0%)
FIRST INCIDENCE					---	---	731 (T)	---
STATISTICAL TESTS								
LIFE TABLE					P=0.647N	(e)	P=0.255	(e)
POLY 3					P=0.663N	(e)	P=0.240	(e)
POLY 1.5					P=0.663N	(e)	P=0.239	(e)
POLY 6					P=0.661N	(e)	P=0.241	(e)
LOGISTIC REGRESSION					(e)	(e)	P=0.255	(e)
COCH-ARM / FISHERS					P=0.652N	(e)	P=0.247	(e)

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
Uterus Leiomyoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)					0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)					0/47.55	0/46.36	2/48.03	0/45.40
POLY-3 PERCENT (g)					0.0%	0.0%	4.2%	0.0%
TERMINAL (d)					0/39 (0%)	0/36 (0%)	2/42 (5%)	0/39 (0%)
FIRST INCIDENCE					---	---	731 (T)	---
STATISTICAL TESTS								
LIFE TABLE					P=0.647N	(e)	P=0.255	(e)
POLY 3					P=0.663N	(e)	P=0.240	(e)
POLY 1.5					P=0.663N	(e)	P=0.239	(e)
POLY 6					P=0.661N	(e)	P=0.241	(e)
LOGISTIC REGRESSION					(e)	(e)	P=0.255	(e)
COCH-ARM / FISHERS					P=0.652N	(e)	P=0.247	(e)

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
All Organs Hemangiosarcoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	2/50 (4%)	1/50 (2%)	1/50 (2%)	3/50 (6%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/46.27	3/45.21	2/45.60	1/44.78	1/47.55	3/46.37	3/48.03	0/45.40
POLY-3 PERCENT (g)	6.5%	6.6%	4.4%	2.2%	2.1%	6.5%	6.3%	0.0%
TERMINAL (d)	1/35 (3%)	3/40 (8%)	1/40 (3%)	0/37 (0%)	1/39 (3%)	2/36 (6%)	3/42 (7%)	0/39 (0%)
FIRST INCIDENCE	668	729 (T)	606	711	731 (T)	730	731 (T)	---
STATISTICAL TESTS								
LIFE TABLE	P=0.237N	P=0.619N	P=0.490N	P=0.314N	P=0.165N	P=0.281	P=0.332	P=0.500N
POLY 3	P=0.232N	P=0.652	P=0.507N	P=0.317N	P=0.185N	P=0.296	P=0.309	P=0.509N
POLY 1.5	P=0.227N	P=0.650	P=0.504N	P=0.312N	P=0.183N	P=0.300	P=0.308	P=0.508N
POLY 6	P=0.237N	P=0.657	P=0.506N	P=0.321N	P=0.184N	P=0.292	P=0.312	P=0.509N
LOGISTIC REGRESSION	P=0.224N	P=0.657	P=0.496N	P=0.308N	P=0.165N	P=0.285	P=0.332	(e)
COCH-ARM / FISHERS	P=0.223N	P=0.661N	P=0.500N	P=0.309N	P=0.171N	P=0.309	P=0.309	P=0.500N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
All Organs Hemangiosarcoma or Hemangioma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	4/50 (8%)	3/50 (6%)	3/50 (6%)	1/50 (2%)	1/50 (2%)	3/50 (6%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	4/46.27	3/45.21	3/45.60	1/44.78	1/47.55	3/46.37	3/48.03	1/45.89
POLY-3 PERCENT (g)	8.6%	6.6%	6.6%	2.2%	2.1%	6.5%	6.3%	2.2%
TERMINAL (d)	2/35 (6%)	3/40 (8%)	2/40 (5%)	0/37 (0%)	1/39 (3%)	2/36 (6%)	3/42 (7%)	0/39 (0%)
FIRST INCIDENCE	668	729 (T)	606	711	731 (T)	730	731 (T)	585
STATISTICAL TESTS								
LIFE TABLE	P=0.168N	P=0.449N	P=0.471N	P=0.185N	P=0.385N	P=0.281	P=0.332	P=0.751
POLY 3	P=0.164N	P=0.513N	P=0.508N	P=0.189N	P=0.405N	P=0.296	P=0.309	P=0.753
POLY 1.5	P=0.159N	P=0.514N	P=0.505N	P=0.185N	P=0.404N	P=0.300	P=0.308	P=0.753
POLY 6	P=0.169N	P=0.507N	P=0.507N	P=0.192N	P=0.400N	P=0.292	P=0.312	P=0.754
LOGISTIC REGRESSION	P=0.159N	P=0.506N	P=0.499N	P=0.184N	P=0.393N	P=0.285	P=0.332	P=0.737N
COCH-ARM / FISHERS	P=0.156N	P=0.500N	P=0.500N	P=0.181N	P=0.389N	P=0.309	P=0.309	P=0.753N

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
All Organs								
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	6/50 (12%)	3/50 (6%)	13/50 (26%)	15/50 (30%)	10/50 (20%)	7/50 (14%)
POLY-3 RATE (b)	3/46.18	1/45.21	6/45.92	3/44.71	13/47.87	15/47.00	10/48.03	7/45.68
POLY-3 PERCENT (g)	6.5%	2.2%	13.1%	6.7%	27.2%	31.9%	20.8%	15.3%
TERMINAL (d)	2/35 (6%)	1/40 (3%)	4/40 (10%)	3/37 (8%)	10/39 (26%)	13/36 (36%)	10/42 (24%)	5/39 (13%)
FIRST INCIDENCE	669	729 (T)	606	729 (T)	680	533	731 (T)	666
STATISTICAL TESTS								
LIFE TABLE	P=0.507	P=0.274N	P=0.281	P=0.646N	P=0.043N*	P=0.329	P=0.258N	P=0.117N
POLY 3	P=0.507	P=0.313N	P=0.239	P=0.647	P=0.058N	P=0.389	P=0.313N	P=0.126N
POLY 1.5	P=0.518	P=0.314N	P=0.240	P=0.653	P=0.057N	P=0.400	P=0.316N	P=0.123N
POLY 6	P=0.493	P=0.308N	P=0.243	P=0.642	P=0.055N	P=0.372	P=0.310N	P=0.125N
LOGISTIC REGRESSION	P=0.517	P=0.310N	P=0.243	P=0.649	P=0.055N	P=0.373	P=0.286N	P=0.126N
COCH-ARM / FISHERS	P=0.522	P=0.309N	P=0.243	P=0.661N	P=0.047N*	P=0.412	P=0.318N	P=0.105N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
All Organs								
Benign Tumors								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	30/50 (60%)	28/50 (56%)	30/50 (60%)	39/50 (78%)	25/50 (50%)	24/50 (48%)	28/50 (56%)	39/50 (78%)
POLY-3 RATE (b)	30/47.38	28/45.62	30/45.60	39/47.37	25/47.96	24/47.85	28/48.81	39/47.15
POLY-3 PERCENT (g)	63.3%	61.4%	65.8%	82.3%	52.1%	50.2%	57.4%	82.7%
TERMINAL (d)	23/35 (66%)	25/40 (63%)	28/40 (70%)	31/37 (84%)	22/39 (56%)	17/36 (47%)	25/42 (60%)	33/39 (85%)
FIRST INCIDENCE	622	663	642	527	680	602	600	519
STATISTICAL TESTS								
LIFE TABLE	P=0.010 *	P=0.205N	P=0.319N	P=0.102	P=0.002 **	P=0.514	P=0.483	P=0.004 **
POLY 3	P=0.009 **	P=0.508N	P=0.487	P=0.027 *	P<0.001 **	P=0.505N	P=0.376	P<0.001 **
POLY 1.5	P=0.010 *	P=0.497N	P=0.531	P=0.030 *	P<0.001 **	P=0.504N	P=0.362	P<0.001 **
POLY 6	P=0.009 **	P=0.508N	P=0.447	P=0.025 *	P<0.001 **	P=0.500N	P=0.398	P<0.001 **
LOGISTIC REGRESSION	P=0.004 **	P=0.440N	P=0.515	P=0.022 *	P<0.001 **	P=0.560N	P=0.377	P<0.001 **
COCH-ARM / FISHERS	P=0.011 *	P=0.420N	P=0.581N	P=0.041 *	P<0.001 **	P=0.500N	P=0.344	P=0.003 **

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - PROPYLENE GLYCOL MONO-T-BUTYL ETHER

Terminal Sacrifice at 105 weeks

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
All Organs Malignant Tumors								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	22/50 (44%)	20/50 (40%)	26/50 (52%)	18/50 (36%)	23/50 (46%)	30/50 (60%)	21/50 (42%)	23/50 (46%)
POLY-3 RATE (b)	22/48.48	20/46.26	26/49.55	18/46.52	23/49.00	30/49.37	21/48.89	23/47.44
POLY-3 PERCENT (g)	45.4%	43.2%	52.5%	38.7%	46.9%	60.8%	43.0%	48.5%
TERMINAL (d)	11/35 (31%)	16/40 (40%)	17/40 (43%)	12/37 (32%)	15/39 (39%)	18/36 (50%)	17/42 (41%)	17/39 (44%)
FIRST INCIDENCE	610	568	451	560	624	533	600	440
STATISTICAL TESTS								
LIFE TABLE	P=0.290N	P=0.311N	P=0.409	P=0.286N	P=0.329N	P=0.105	P=0.337N	P=0.552
POLY 3	P=0.263N	P=0.499N	P=0.309	P=0.326N	P=0.388N	P=0.119	P=0.424N	P=0.521
POLY 1.5	P=0.239N	P=0.483N	P=0.301	P=0.301N	P=0.378N	P=0.117	P=0.422N	P=0.528
POLY 6	P=0.294N	P=0.514N	P=0.317	P=0.357N	P=0.395N	P=0.122	P=0.429N	P=0.516
LOGISTIC REGRESSION	P=0.226N	P=0.442N	P=0.307	P=0.269N	P=0.301N	P=0.144	P=0.431N	P=0.565
COCH-ARM / FISHERS	P=0.227N	P=0.420N	P=0.274	P=0.270N	P=0.319N	P=0.115	P=0.420N	P=0.579N

Dose	Males CONTROL	Males 75 PPM	Males 300 PPM	Males 1200 PPM	Females CONTROL	Females 75 PPM	Females 300 PPM	Females 1200 PPM
All Organs Malignant and Benign Tumors								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	41/50 (82%)	38/50 (76%)	41/50 (82%)	43/50 (86%)	37/50 (74%)	39/50 (78%)	37/50 (74%)	47/50 (94%)
POLY-3 RATE (b)	41/49.06	38/46.51	41/49.55	43/48.25	37/49.00	39/49.60	37/49.17	47/48.32
POLY-3 PERCENT (g)	83.6%	81.7%	82.8%	89.1%	75.5%	78.6%	75.3%	97.3%
TERMINAL (d)	27/35 (77%)	33/40 (83%)	32/40 (80%)	33/37 (89%)	29/39 (74%)	26/36 (72%)	32/42 (76%)	38/39 (97%)
FIRST INCIDENCE	610	568	451	527	624	533	600	440
STATISTICAL TESTS								
LIFE TABLE	P=0.225	P=0.140N	P=0.329N	P=0.508	P=0.036 *	P=0.269	P=0.393N	P=0.035 *
POLY 3	P=0.199	P=0.512N	P=0.563N	P=0.306	P<0.001 **	P=0.448	P=0.582N	P<0.001 **
POLY 1.5	P=0.216	P=0.461N	P=0.562N	P=0.343	P<0.001 **	P=0.430	P=0.584N	P<0.001 **
POLY 6	P=0.182	P=0.570N	P=0.581N	P=0.265	P<0.001 **	P=0.477	P=0.582N	P<0.001 **
LOGISTIC REGRESSION	P=0.200	P=0.400N	P=0.599	P=0.339	P=0.002 **	P=0.410	P=0.567N	P<0.001 **
COCH-ARM / FISHERS	P=0.210	P=0.312N	P=0.602N	P=0.393	P=0.005 **	P=0.408	P=0.590N	P=0.006 **

(a) Number of tumor-bearing animals / number of animals examined at site.
(b) Number of tumor-bearing animals / Poly-3 number
(d) Observed incidence at terminal kill.
(f) 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.
Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors. The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates
For all tests a negative trend is indicated by N
(e) Value of Statistic cannot be computed.
(g) Poly-3 adjusted lifetime tumor incidence.
(I) Interim sacrifice
(T) Terminal sacrifice
Tumor rates based on number of animals necropsied.
* To the right of any statistical result, indicates significance at (P<=0.05).
** To the right of any statistical result, indicates significance at (P<=0.01).

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

FINAL/MICE

Facility: Battelle Northwest

Chemical CAS #: 57018-52-7

Lock Date: 12/11/00

Cage Range: All

Reasons For Removal: All

Removal Date Range: All

Treatment Groups: Include All

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
DISPOSITION SUMMARY				
Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	8	10	6	4
Natural Death	3	3	2	6
Accidently Killed		1		1
Survivors				
Terminal Sacrifice	39	36	41	38
Natural Death			1	1
Animals Examined Microscopically	50	50	50	49
ALIMENTARY SYSTEM				
Gallbladder	(40)	(39)	(43)	(33)
Cyst	1 [4.0]			
Intestine Large, Colon	(48)	(49)	(50)	(48)
Infiltration Cellular, Mixed Cell				1 [3.0]
Intestine Large, Rectum	(48)	(49)	(50)	(48)
Necrosis				1 [1.0]
Intestine Large, Cecum	(49)	(48)	(49)	(46)
Necrosis			2 [1.5]	
Intestine Small, Duodenum	(49)	(47)	(50)	(46)
Infiltration Cellular, Mixed Cell				1 [2.0]
Epithelium, Hyperplasia			1 [1.0]	
Intestine Small, Jejunum	(49)	(48)	(48)	(47)
Infiltration Cellular, Mixed Cell			1 [3.0]	
Inflammation, Suppurative				1 [4.0]
Necrosis				1 [2.0]
Intestine Small, Ileum	(49)	(48)	(48)	(45)
Hyperplasia	1 [4.0]			
Infiltration Cellular, Mixed Cell	2 [2.0]	1 [2.0]	3 [2.3]	1 [3.0]
Necrosis				2 [2.0]
Epithelium, Hyperplasia	1 [3.0]			
Liver	(49)	(50)	(50)	(49)
Angiectasis			1 [2.0]	
Basophilic Focus	3	4	4	2
Clear Cell Focus	4	4	6	5
Eosinophilic Focus	11	10	9	27
Fatty Change	2 [2.5]	1 [2.0]	1 [3.0]	1 [3.0]
Fatty Change, Focal		1 [2.0]		
Hematopoietic Cell Proliferation			1 [1.0]	

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
ALIMENTARY SYSTEM - CONT				
Infarct			1 [4.0]	
Inflammation, Granulomatous	23 [1.0]	9 [1.1]	17 [1.1]	12 [1.1]
Tension Lipidosis	4 [2.0]	3 [1.7]	6 [1.5]	4 [1.5]
Thrombosis			1 [4.0]	
Bile Duct, Cyst	1 [2.0]			
Bile Duct, Hyperplasia		1 [2.0]	1 [2.0]	
Centrilobular, Necrosis		3 [2.3]		
Hepatocyte, Mitotic Alteration		1 [2.0]		
Mesentery	(17)	(21)	(13)	(2)
Infiltration Cellular, Mast Cell	1 [2.0]			
Fat, Congestion	1 [1.0]			
Fat, Necrosis	14 [2.0]	19 [2.1]	12 [2.0]	2 [2.0]
Oral Mucosa	(1)			
Inflammation	1 [2.0]			
Pancreas	(49)	(50)	(50)	(48)
Atrophy	1 [2.0]		2 [2.5]	
Basophilic Focus	1 [1.0]	1 [2.0]	1 [2.0]	
Duct, Cyst			1 [4.0]	
Salivary Glands	(50)	(50)	(50)	(49)
Atrophy				1 [2.0]
Stomach, Forestomach	(49)	(50)	(50)	(48)
Hyperplasia, Squamous	3 [1.0]	5 [1.6]	1 [2.0]	6 [1.8]
Infiltration Cellular, Mast Cell			1 [2.0]	
Infiltration Cellular, Mixed Cell	1 [2.0]			
Inflammation	2 [1.5]	5 [1.2]	2 [1.0]	6 [1.5]
Ulcer	2 [2.5]		1 [2.0]	4 [1.5]
Stomach, Glandular	(49)	(48)	(50)	(48)
Mineralization	2 [1.5]	1 [1.0]	1 [3.0]	1 [1.0]
Tooth	(50)	(50)	(50)	(49)
Inflammation, Chronic Active	1 [1.0]	2 [3.0]	1 [2.0]	7 [2.3]
Malformation	1 [1.0]	1 [3.0]		
CARDIOVASCULAR SYSTEM				
Blood Vessel			(2)	
Inflammation, Chronic			1 [3.0]	
Heart	(50)	(50)	(50)	(49)
Cardiomyopathy	5 [1.2]	4 [1.3]	8 [1.0]	3 [1.0]
Inflammation, Chronic		1 [2.0]		
Mineralization	1 [1.0]	1 [2.0]		
Thrombosis				1 [2.0]
Artery, Inflammation, Chronic Active	1 [2.0]			

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
CARDIOVASCULAR SYSTEM - CONT				
Endocardium, Hyperplasia		1 [4.0]		
Valve, Inflammation, Suppurative		1 [2.0]		
ENDOCRINE SYSTEM				
Adrenal Cortex	(49)	(50)	(50)	(48)
Hyperplasia	8 [1.9]	3 [1.7]	3 [2.0]	4 [1.8]
Hypertrophy	7 [1.7]	7 [1.7]	1 [2.0]	2 [2.0]
Necrosis	1 [4.0]	1 [1.0]		
Vacuolization Cytoplasmic		3 [2.7]	3 [3.0]	
Adrenal Medulla	(47)	(49)	(50)	(48)
Hyperplasia	2 [2.5]	4 [2.3]	1 [3.0]	3 [1.7]
Hypertrophy				1 [2.0]
Necrosis	1 [4.0]			
Islets, Pancreatic	(49)	(50)	(50)	(48)
Hyperplasia	1 [2.0]			1 [3.0]
Pituitary Gland	(48)	(49)	(47)	(46)
Pars Distalis, Angiectasis	1 [3.0]		1 [2.0]	1 [2.0]
Pars Distalis, Hyperplasia	16 [2.4]	11 [2.1]	16 [2.8]	11 [2.1]
Thyroid Gland	(49)	(50)	(50)	(48)
Follicular Cell, Hyperplasia	2 [1.5]	1 [2.0]	3 [1.7]	1 [2.0]
GENERAL BODY SYSTEM				
Peritoneum		(1)	(2)	
Inflammation, Chronic, Suppurative		1 [4.0]		
GENITAL SYSTEM				
Clitoral Gland	(42)	(43)	(48)	(45)
Inflammation, Chronic		1 [3.0]		
Ovary	(50)	(49)	(49)	(48)
Angiectasis	1 [3.0]	1 [2.0]		
Atrophy				1 [2.0]
Cyst	12 [2.0]	12 [2.4]	12 [2.3]	11 [2.3]
Inflammation, Chronic Active		1 [3.0]		
Thrombosis			1 [4.0]	
Uterus	(50)	(50)	(50)	(48)
Angiectasis	3 [1.7]	1 [2.0]	4 [3.5]	2 [2.5]
Inflammation, Suppurative		1 [3.0]	2 [3.5]	2 [3.0]

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
GENITAL SYSTEM - CONT				
Thrombosis		2 [2.5]		
Endometrium, Fibrosis	1 [3.0]			
Endometrium, Hyperplasia, Cystic	46 [2.7]	48 [2.5]	48 [3.0]	45 [3.3]
HEMATOPOIETIC SYSTEM				
Bone Marrow	(49)	(50)	(50)	(48)
Thrombosis				1 [3.0]
Lymph Node	(4)	(8)	(6)	(2)
Angiectasis		2 [3.5]		
Ectasia			1 [4.0]	
Lumbar, Angiectasis	1 [3.0]			
Renal, Angiectasis	1 [3.0]			
Renal, Ectasia	1 [3.0]			
Lymph Node, Mandibular	(44)	(45)	(45)	(34)
Hyperplasia, Lymphoid				1 [4.0]
Infiltration Cellular, Plasma Cell				1 [2.0]
Lymph Node, Mesenteric	(48)	(48)	(48)	(48)
Angiectasis	1 [3.0]	2 [3.0]	2 [3.0]	1 [2.0]
Infiltration Cellular, Plasma Cell		1 [3.0]		
Inflammation, Granulomatous			1 [2.0]	
Inflammation, Suppurative				1 [3.0]
Lymph Node, Mediastinal	(40)	(41)	(41)	(31)
Hemorrhage	1 [2.0]			
Spleen	(49)	(50)	(50)	(48)
Fibrosis		1 [2.0]		
Hematopoietic Cell Proliferation	4 [3.0]	4 [3.0]	2 [3.0]	3 [2.7]
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(49)
Hyperplasia, Squamous	1 [2.0]			
Infiltration Cellular, Mixed Cell	1 [2.0]	3 [1.3]	2 [1.5]	
Inflammation, Acute				1 [2.0]
Inflammation, Chronic Active				1 [1.0]
Subcutaneous Tissue, Inflammation, Acute		1 [3.0]		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(49)

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
MUSCULOSKELETAL SYSTEM - CONT				
Synovial Tissue, Hyperplasia			1 [4.0]	
Skeletal Muscle	(1)	(2)		
Hemorrhage	1 [2.0]			
Inflammation, Acute		1 [3.0]		
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(49)
Meninges, Infiltration Cellular, Mononuclear Cell	1 [2.0]			
Spinal Cord	(2)			
Hemorrhage	1 [2.0]			
RESPIRATORY SYSTEM				
Larynx	(50)	(50)	(50)	(48)
Metaplasia, Squamous	1 [2.0]			
Lung	(50)	(50)	(50)	(49)
Foreign Body			1	
Inflammation, Granulomatous				2 [1.0]
Mineralization			1 [1.0]	
Thrombosis	1 [1.0]			2 [2.0]
Alveolar Epithelium, Hyperplasia	3 [2.0]	2 [2.0]	4 [1.3]	3 [2.0]
Alveolus, Infiltration Cellular, Histiocyte	2 [1.0]	1 [1.0]		3 [2.0]
Artery, Inflammation, Acute				2 [2.0]
Nose	(50)	(50)	(49)	(49)
Inflammation, Acute		1 [4.0]		
Inflammation, Suppurative	3 [1.7]		1 [1.0]	1 [1.0]
Respiratory Epithelium, Metaplasia, Squamous	2 [2.0]			
Respiratory Epithelium, Necrosis	2 [1.5]			1 [2.0]
Pleura		(1)	(1)	
Hyperplasia		1 [2.0]		
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(48)
Cataract				2 [3.0]
Anterior Chamber, Inflammation, Acute	1 [1.0]			1 [1.0]
Cornea, Erosion				3 [2.3]
Cornea, Hyperplasia, Squamous	1 [2.0]	2 [1.0]		2 [2.0]

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE FEMALE	CONTROL	75 PPM	300 PPM	1200 PPM
SPECIAL SENSES SYSTEM - CONT				
Cornea, Inflammation, Acute				1 [3.0]
Cornea, Inflammation, Chronic Active	1 [2.0]	2 [3.0]		4 [2.0]
Cornea, Mineralization	1 [2.0]	2 [2.0]		20 [2.0]
Cornea, Ulcer		1 [2.0]		1 [2.0]
Retrobulbar, Inflammation, Granulomatous				1 [3.0]
Harderian Gland	(50)	(50)	(50)	(49)
Hyperplasia	3 [2.3]	3 [2.7]	4 [1.5]	4 [2.0]
URINARY SYSTEM				
Kidney	(49)	(50)	(50)	(48)
Infarct	1 [2.0]		2 [2.0]	3 [2.0]
Metaplasia, Osseous	2 [2.0]	1 [1.0]	1 [2.0]	1 [1.0]
Nephropathy	34 [1.2]	34 [1.3]	32 [1.3]	34 [1.3]
Thrombosis			1 [4.0]	
Pelvis, Dilatation			1 [4.0]	
Renal Tubule, Degeneration, Hyaline	1 [2.0]			1 [2.0]
Renal Tubule, Necrosis			1 [2.0]	
Urinary Bladder	(50)	(49)	(50)	(47)
Inflammation, Acute				1 [2.0]
Transitional Epithelium, Hyperplasia	1 [2.0]			

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b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
DISPOSITION SUMMARY				
Animals Initially In Study	50	50	50	50
Early Deaths				
Natural Death	11	4	4	5
Moribund Sacrifice	4	6	6	8
Survivors				
Terminal Sacrifice	35	40	40	37
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Gallbladder	(38)	(41)	(39)	(40)
Degeneration, Hyaline		1 [2.0]	2 [1.5]	
Intestine Large, Colon	(46)	(48)	(48)	(47)
Serosa, Inflammation, Granulomatous		1 [3.0]		
Intestine Large, Rectum	(46)	(48)	(48)	(46)
Infiltration Cellular, Mixed Cell	1 [2.0]			
Intestine Large, Cecum	(43)	(47)	(48)	(48)
Necrosis	1 [3.0]	1 [2.0]		
Intestine Small, Jejunum	(42)	(47)	(47)	(45)
Infiltration Cellular, Mixed Cell	2 [2.5]		2 [2.5]	
Inflammation, Granulomatous	1 [3.0]	1 [3.0]		
Necrosis			1 [2.0]	
Epithelium, Hyperplasia	1 [2.0]			
Intestine Small, Ileum	(43)	(47)	(46)	(46)
Infiltration Cellular, Mixed Cell	4 [2.5]	2 [2.0]	2 [2.0]	1 [2.0]
Inflammation, Acute			1 [3.0]	
Inflammation, Chronic Active		1 [2.0]	1 [2.0]	
Necrosis			1 [1.0]	
Epithelium, Hyperplasia	1 [2.0]	1 [3.0]		
Liver	(50)	(49)	(50)	(50)
Basophilic Focus	6	11	16	4
Clear Cell Focus	20	18	16	17
Eosinophilic Focus	9	14	11	29
Fatty Change		1 [1.0]		2 [1.5]
Hematopoietic Cell Proliferation	1 [2.0]	1 [1.0]	1 [1.0]	
Infarct	2 [3.0]	1 [2.0]	1 [3.0]	3 [3.0]
Inflammation, Granulomatous	9 [1.0]	12 [1.0]	11 [1.1]	3 [1.3]
Mixed Cell Focus				4
Tension Lipidosis	1 [2.0]	2 [2.0]	4 [1.8]	2 [2.0]
Centrilobular, Necrosis	1 [1.0]	1 [3.0]	1 [3.0]	

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b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
ALIMENTARY SYSTEM - CONT				
Hepatocyte, Multinucleated	27 [1.0]	23 [1.0]	24 [1.0]	46 [1.8]
Mesentery	(14)	(16)	(13)	(11)
Inflammation, Granulomatous	2 [2.5]	1 [3.0]	4 [2.3]	1 [2.0]
Artery, Inflammation			1 [3.0]	2 [2.5]
Fat, Necrosis	10 [1.9]	14 [2.0]	7 [2.0]	7 [2.1]
Pancreas	(48)	(49)	(50)	(50)
Atrophy		1 [1.0]		
Basophilic Focus				1 [2.0]
Stomach, Forestomach	(48)	(49)	(50)	(50)
Hyperkeratosis			1 [2.0]	
Hyperplasia, Squamous				1 [2.0]
Inflammation	2 [1.0]	3 [1.0]	9 [1.1]	9 [1.2]
Ulcer				1 [1.0]
Artery, Inflammation, Chronic Active			1 [3.0]	
Epithelium, Hyperplasia, Squamous	2 [1.5]	5 [1.8]	9 [2.0]	7 [1.7]
Epithelium, Ulcer	1 [1.0]	1 [2.0]	3 [2.0]	3 [1.0]
Stomach, Glandular	(46)	(48)	(50)	(48)
Hyperplasia	1 [2.0]			
Metaplasia, Squamous	1 [2.0]			
Mineralization	1 [1.0]	1 [2.0]	1 [2.0]	1 [1.0]
Necrosis		2 [1.5]	1 [1.0]	
Tooth	(50)	(50)	(50)	(50)
Inflammation, Chronic Active	3 [1.3]	5 [2.4]	4 [2.3]	15 [1.7]
Malformation	24 [1.3]	15 [1.0]	15 [1.3]	16 [1.1]
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	9 [1.0]	8 [1.0]	11 [1.4]	7 [1.0]
Mineralization	1 [1.0]	1 [1.0]		
Necrosis	2 [2.5]			
Thrombosis			1 [3.0]	1 [2.0]
Artery, Inflammation, Chronic Active			3 [2.3]	
ENDOCRINE SYSTEM				
Adrenal Cortex	(48)	(49)	(50)	(50)
Hyperplasia	11 [1.8]	9 [2.1]	14 [2.1]	7 [1.7]
Hypertrophy	34 [2.0]	32 [2.0]	29 [1.9]	18 [1.5]
Adrenal Medulla	(47)	(49)	(49)	(49)
Hyperplasia		1 [2.0]	1 [2.0]	2 [2.0]

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
ENDOCRINE SYSTEM - CONT				
Infiltration Cellular, Polymorphonuclear			1 [3.0]	
Islets, Pancreatic	(48)	(49)	(50)	(50)
Hyperplasia		1 [2.0]		
Pituitary Gland	(43)	(48)	(50)	(48)
Cyst		1 [2.0]		
Pars Distalis, Hyperplasia		1 [3.0]	4 [1.8]	1 [2.0]
Thyroid Gland	(48)	(48)	(49)	(49)
Follicular Cell, Hyperplasia			1 [2.0]	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm	1 [2.0]	1 [2.0]		
Inflammation, Chronic		1 [2.0]		
Preputial Gland	(50)	(50)	(50)	(50)
Ectasia	2 [2.0]	1 [3.0]	1 [3.0]	
Hyperplasia, Squamous	1 [2.0]			2 [1.5]
Inflammation, Chronic		2 [3.0]	2 [2.5]	
Inflammation, Suppurative		3 [3.3]	2 [2.0]	2 [2.5]
Prostate	(49)	(49)	(47)	(50)
Inflammation, Suppurative			1 [2.0]	
Artery, Inflammation, Chronic Active		1 [3.0]	1 [3.0]	
Seminal Vesicle	(47)	(49)	(49)	(49)
Inflammation, Chronic		2 [2.5]	1 [3.0]	
Testes	(50)	(50)	(50)	(50)
Amyloid Deposition		1 [3.0]		
Atrophy		1 [1.0]	1 [4.0]	
Mineralization	1 [2.0]			
Germinal Epithelium, Degeneration	1 [2.0]			1 [2.0]
HEMATOPOIETIC SYSTEM				
Bone Marrow	(49)	(49)	(50)	(50)
Thrombosis				1 [2.0]
Lymph Node, Bronchial	(32)	(36)	(36)	(35)
Infiltration Cellular, Plasma Cell	1 [2.0]			

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE

	CONTROL	75 PPM	300 PPM	1200 PPM
HEMATOPOIETIC SYSTEM - CONT				
Lymph Node, Mandibular				
Infiltration Cellular, Plasma Cell	(28)	(38)	(30)	(25)
Lymph Node, Mesenteric				
Angiectasis	(48)	(49)	(49)	(50)
Infiltration Cellular, Plasma Cell	2 [3.5]	1 [4.0]	1 [3.0]	1 [4.0]
Infiltration Cellular, Mixed Cell	1 [4.0]		4 [3.0]	
Pigmentation		1 [2.0]		
Lymph Node, Mediastinal				
Inflammation, Granulomatous	(39)	(39)	(43)	(36)
Spleen				
Angiectasis	(48)	(48)	(50)	(50)
Hematopoietic Cell Proliferation	4 [2.8]	2 [3.0]	2 [2.5]	1 [2.0]
Hyperplasia, Lymphoid				2 [2.0]
Infiltration Cellular, Histiocyte	1 [3.0]			1 [2.0]
INTEGUMENTARY SYSTEM				
Skin				
Infiltration Cellular, Mixed Cell	(49)	(50)	(50)	(50)
Inflammation, Chronic Active	4 [3.0]	1 [2.0]	6 [3.2]	5 [2.8]
Epidermis, Hyperplasia		1 [4.0]		1 [2.0]
Subcutaneous Tissue, Edema	1 [3.0]			
Subcutaneous Tissue, Hemorrhage	1 [3.0]			
MUSCULOSKELETAL SYSTEM				
Bone				
Fibrous Osteodystrophy	(50)	(50)	(50)	(50)
	1 [2.0]			
NERVOUS SYSTEM				
Brain				
Necrosis	(50)	(50)	(50)	(50)
Artery, Inflammation, Chronic Active	1 [1.0]		1 [2.0]	
RESPIRATORY SYSTEM				
Larynx				
Artery, Inflammation, Chronic Active	(49)	(50)	(50)	(50)
			1 [3.0]	

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

NTP Experiment-Test: 90004-06
Study Type: CHRONIC
Route: RESPIRATORY EXPOSURE WHOLE BODY

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
RESPIRATORY SYSTEM - CONT	(50)	(50)	(50)	(50)
Lung				
Hemorrhage		1 [2.0]		1 [1.0]
Inflammation, Granulomatous		1 [1.0]	1 [3.0]	1 [3.0]
Inflammation, Suppurative		1 [2.0]		
Mineralization		3 [2.0]		
Thrombosis		4 [1.8]	4 [1.5]	2 [1.5]
Alveolar Epithelium, Hyperplasia	6 [1.7]			
Alveolus, Infiltration Cellular, Histiocyte	1 [3.0]			
Nose	(50)	(49)	(50)	(50)
Amyloid Deposition		1 [4.0]		
Inflammation, Suppurative	5 [2.0]		4 [2.0]	6 [1.5]
Olfactory Epithelium, Atrophy			1 [3.0]	
Respiratory Epithelium, Metaplasia, Squamous				1 [1.0]
Respiratory Epithelium, Necrosis			1 [4.0]	1 [1.0]
Pleura	(1)		(1)	
Necrosis, Fatty			1 [1.0]	
Trachea	(48)	(48)	(50)	(50)
Degeneration, Hyaline			1 [3.0]	
Inflammation, Suppurative			1 [3.0]	
SPECIAL SENSES SYSTEM	(48)	(49)	(50)	(50)
Eye				
Cornea, Erosion	1 [1.0]			1 [1.0]
Cornea, Hyperplasia, Squamous	1 [1.0]		1 [1.0]	1 [2.0]
Cornea, Inflammation, Chronic Active				1 [2.0]
Cornea, Mineralization				3 [1.7]
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia	10 [2.5]	3 [2.7]	5 [2.4]	1 [3.0]
Zymbal's Gland	(35)	(35)	(36)	(32)
Hyperplasia	1 [2.0]			
URINARY SYSTEM	(50)	(49)	(50)	(50)
Kidney				
Amyloid Deposition	1 [1.0]	1 [4.0]	2 [2.0]	7 [2.6]
Cyst	3 [3.0]	1 [2.0]	3 [2.0]	1 [4.0]
Infarct		3 [2.0]		
Inflammation, Chronic, Suppurative	3 [1.0]	1 [2.0]	2 [1.5]	
Metaplasia, Osseous		6 [1.2]		
Mineralization		1 [1.0]		

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
PROPYLENE GLYCOL MONO-T-BUTYL ETHER

B6C3F1 MICE MALE	CONTROL	75 PPM	300 PPM	1200 PPM
URINARY SYSTEM - CONT				
Nephropathy	41 [1.3]	40 [1.4]	44 [1.5]	36 [1.4]
Artery, Inflammation, Chronic Active			2 [2.0]	1 [3.0]
Papilla, Inflammation, Suppurative			1 [2.0]	
Pelvis, Dilatation			1 [1.0]	2 [2.5]
Renal Tubule, Hyperplasia	2 [1.5]		1 [1.0]	
Renal Tubule, Necrosis	1 [2.0]			
Transitional Epithelium, Hyperplasia				2 [2.0]
Urinary Bladder	(48)	(48)	(49)	(50)
Inflammation, Chronic Active			1 [3.0]	
Artery, Inflammation, Chronic Active		1 [2.0]	1 [2.0]	

a Number of animals examined microscopically at site and number of animals with lesion
b Average severity grade (1-minimal;2-mild;3-moderate;4-marked)

---------- END OF REPORT ----------