FYI-0702-01430

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July 03, 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 Topical study on TRIETHANOLAMINE (102-71-6) 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 Mice
cc: Central Data Management

PATHOLOGY WORKING GROUP
CHAIRPERSON'S REPORT

THE CHRONIC DERMAL TOXICITY/CARCINOGENICITY STUDY OF TRIETHANOLAMINE (TEA) (C61621E/0510914) IN B6C3F$_1$ MICE

DATE OF PWG: February 19, 2002

LOCATION OF PWG: NIEHS, Research Triangle Park, NC

PARTICIPANTS:

Drs. R. Brown (Research Pathology Services, Inc.), G. Flake (NIEHS), A. Nyska (NIEHS), G. Parker (ILS-PWG Chairperson), G. Pearse (NIEHS), C. Shackleford (EPL), G. Willson (EPL), and R. Bahnemann (BASF-observer).

SUMMARY OF FINDINGS FROM PWG

The PWG was convened to evaluate selected H & E slides from a two-year chronic study of triethanolamine (TEA) administered by dermal application to B6C3F$_1$ mice.

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

- Increased incidence of hepatocellular neoplasms and foci in all treated female groups
- Increased incidence of eosinophilic foci in the livers of males from the 630 and 2000 mg/kg groups, with no treatment-related pattern in the incidence of all hepatocellular foci combined in males.
- Insignificant increase in the incidence of hepatoblastomas in 2000 mg/kg males.
- Increased incidence of inflammation and epidermal hyperplasia at the skin site of application in treated males and females.
- Unexplained increase in the incidence and severity of lesions at the skin SOA in the repeat study as compared to the original study.

INTRODUCTION

Triethanolamine is produced in large quantities (86 million kilograms in 1991) and has widespread use in cosmetic formulations, cutting oils, and the manufacture of emulsifiers, dispersing agents, synthetic resins, plasticizers, adhesives and sealants. The major occupational exposure risk is through cutaneous adsorption. The Cosmetic Ingredient Review Expert Panel conclude that the use of mono-, di-, and triethanolamine is safe in cosmetic formulations designed for brief, discontinuous use followed by rinsing of the skin, and concluded that ethanolamine concentration should not exceed 5% in cosmetic products intended for prolonged skin contact. In the presence of some nitrogenous compounds, including an antimicrobial agent that is commonly used in cosmetics, di- and triethanolamine may be nitrosated to N-nitrosodiethanolamine, which is a known liver, kidney and nasal carcinogen in laboratory animals. N-nitrosodiethanolamine at concentrations up to 3% has been demonstrated in metal-working cutting oils that contain triethanolamine and sodium nitrate, therefore nitrosating agents have been prohibited in any metalworking fluid containing a triethanolamine salt of a tricarboxylic acid complex. TEA was nominated for study by the National Cancer Institute based on its widespread use in cosmetics and other consumer products, potential for industrial exposure, and its potential for conversion to carcinogenic N-nitrosodiethanolamine.

In the NTP subchronic study ten each male and female mice were topically administered TEA in acetone at 0, 250, 1000 or 2000 mg/kg of body weight, or neat TEA at 4000 mg/kg of body weight, five days a week for 13 weeks. All mice survived to the end of the study and there was no treatment-related alteration in terminal body weight. The only treatment-related clinical findings were scaliness, irritation and discoloration at the site of application in males and females from the 4000 mg/kg group, and skin erosion at the site of application of one male from the 4000 mg/kg group. Absolute kidney and liver weights of 4000 mg/kg males and females were greater than controls. Kidney weight relative to body weight was increased in all dosed female groups and males given 1000 mg/kg or more TEA . Histologic examination revealed acanthosis at the site of application of all dosed groups, with severity increasing with dose level. Inflammation at the site of application was observed in males and females from the 4000 mg/kg group and one female from the 2000 mg/kg group.

STUDY DESIGN

For the chronic study male and female $B6C3F_1$ mice were exposed to TEA via dermal application at concentrations of 0, 200, 630, or 2000 mg/kg (males) or 0, 100, 300, or 1000 mg/kg (females). The study was conducted at Battelle, Columbus, OH. The Study Pathologist (SP) was Dr. M. Ryan. The Quality Assessment Pathologist (QAP) was Dr. G. Willson of EPL. The study design was identical to that used in a previous skin paint study of TEA in mice, also conducted by Batelle Columbus, which was confounded by helicobacter infection.

STUDY RESULTS

Survival: Survival of all treated groups was similar to that of controls.

Clinical observations: Clinical evidence of irritation at the skin site of application (SOA) increased with dose and was more severe in males than females. Time of onset of the skin irritation was related to dose in males, with earlier onset in higher dose groups. Clinical signs consisted of small, brown, crusty, scab-like patches at various locations over the site of application.

Body weights: Group mean body weights of dosed females were similar to control body weights. Body weights of males from the 2000 mg/kg group were decreased compared to controls at Week 21, then returned to control levels until near the end of the study. At study termination the group mean body weight of 2000 mg/kg males was 10.3% less than control body weight.

Necropsy: There was an increased incidence of liver nodules and masses in females of all TEA-treated groups. There was an increased incidence of skin SOA lesions in males of all dose groups and females of the 300 and 1000 mg/kg groups.

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

Liver- increased incidence of hepatocellular adenomas in all treated female groups.

Liver- increased incidence of hepatoblastoma in 2000 mg/kg males

Liver- increased incidence of eosinophilic and mixed cell foci in all treated female groups, and increased incidence of eosinophilic foci in 630 and 2000 mg/kg males.

Treated skin- increased incidence of ulceration, epidermal hyperplasia, dermal or subcutaneous chronic inflammation and epidermal suppurative inflammation in treated mice of both sexes.

CONDUCT OF THE PWG

In preparation for the PWG, the PWG Chairperson reviewed the study pathology tables (summary and individual animal data), the Final Report from the laboratory that conducted the study, the Quality Assessment Report, relevant literature and H&E-stained slides selected for the QA review. In addition to reviewing all slides from the current study that were selected for the QA review, the PWG Chairperson also reviewed liver and skin SOA lesions from the high dose and control males and females from the original study. The Chairperson then selected slides for review by the PWG. The selected slides included the following:

1. liver proliferative lesions from females in which there was some discrepancy in the diagnoses applied by SP, QAP or PWG chairperson.
2. all hepatoblastomas from males
3. the ten most severe skin SOA lesions from the high-dose and control females from the current study, and the ten most severe skin SOA lesions from the high-dose females of the original study. Skin lesions from females rather than males were selected because there was some question regarding the possible relationship of skin lesions and liver lesions in females
4. miscellaneous lesions as selected by the Chairperson

PWG RESULTS

Liver

For the majority of proliferative lesions of the liver there was good agreement between the SP, QAP, and PWG chairperson. However, the QAP felt that many smaller lesions had morphological characteristics consistent with adenoma rather than focus as diagnosed by the SP. The PWG chairperson and PWG agreed with the QAP. The PWG chairperson identified additional marginal proliferative lesions as adenomas rather than foci as diagnosed by the SP and QAP. The PWG was in agreement with the PWG chairperson. Some of these lesions (particularly low and mid-dose females) were not reviewed by the PWG. Since there was good agreement between the PWG and the PWG chairperson, his classification was accepted (action item for NTP when making data changes). Other than the proliferative lesions, toxic change was not identified in the livers. The question was raised as to whether there was a potential correlation between the incidence/severity of skin SOA lesions and the incidence of liver adenomas in treated females (action item for NTP).

Skin, Site of Application (SOA)

The consensus opinion of the PWG was that the lesions at the skin SOA were more severe in the high-dose females than in control females of the current study, and that lesions in the skin SOA of the high-dose females from the current study were more severe than those observed in high-dose females of the original study. Possible factors involved in the difference in severity of skin lesions in the two studies were discussed, but no conclusions were reached. The only substantial difference in study design was the use of NTP2000 diet in the repeat study, as opposed to the NIH07 diet that was used in the original study. The PWG concluded the potential benefit did not justify the expense in harmonizing the diagnosis of "epidermal hyperplasia" in the current study and the diagnosis of "acanthosis" in the original study.

In skin paint studies, a routine section of skin is taken from a specific area within the SOA. If lesions are observed at other areas within the SOA, additional sections are taken. The majority of significant lesions in the skin-SOA of treated females in the current study were focal and

identified in the additional sections rather than in the routine section. Therefore, to determine the severity of change within the entire SOA, the PWG chairperson was asked to review the necropsy records and slides to assess the incidence of gross lesions in affected animals (action item PWG chairperson - attachment 1).

SUMMARY

Female $B6C3F_1$ mice exposed to triethanolamine at 100, 300, or 1000 mg/kg via skin application had an increased incidence of hepatocellular neoplasms and foci of cellular alteration as compared to concurrent controls. Although the incidence of heaptoblastomas in male mice occurred with a positive trend the number of tumors was low and the PWG considered it unlikely to be treatment-related. Triethanolamine-treated male and female mice in the current (repeat) study had an increased incidence of inflammatory lesions at the site of cutaneous application. Lesions at the site of triethanolamine application were more pronounced in the current (repeat) study than in the original study. There was no apparent explanation for the difference in severity of the skin lesions in the two studies.

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

Date 1 Apr 02

Attachment 1

NATIONAL TOXICOLOGY PROGRAM

TR-518 TRIETHANOLAMINE

Pathology Tables - Mice

P03 - Incidence Rates of Non-Neoplastic Lesions

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

P08 - Statistical Analysis of Primary Tumors

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
TRIETHANOLAMINE

FINAL #1/MICE

Facility: Battelle Columbus Laboratory

Chemical CAS #: 102-71-6

Lock Date: 05/31/01

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)
TRIETHANOLAMINE

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
DISPOSITION SUMMARY				
Animals Initially In Study	50	50	50	50
Early Deaths				
Natural Death	7	6	4	7
Moribund Sacrifice	8	10	5	10
Accidently Killed				1
Survivors				
Terminal Sacrifice	34	34	41	32
Natural Death	1			
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Serosa, Inflammation, Chronic			1 (2%)	
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Epithelium, Necrosis	1 (2%)			
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Diverticulum				1 (2%)
Ulcer		1 (2%)		
Peyer's Patch, Hyperplasia	1 (2%)			
Peyer's Patch, Inflammation, Suppurative			1 (2%)	
Serosa, Inflammation, Granulomatous				1 (2%)
Liver	(50)	(50)	(50)	(50)
Angiectasis, Focal			1 (2%)	
Basophilic Focus	4 (8%)		3 (6%)	3 (6%)
Clear Cell Focus	4 (8%)	3 (6%)	3 (6%)	5 (10%)
Eosinophilic Focus	16 (32%)	22 (44%)	28 (56%)	32 (64%)
Fibrosis, Focal	1 (2%)			
Hematopoietic Cell Proliferation	4 (8%)	3 (6%)	3 (6%)	4 (8%)
Hepatodiaphragmatic Nodule		2 (4%)		
Infiltration Cellular, Lymphoid	26 (52%)	30 (60%)	36 (72%)	20 (40%)
Inflammation, Chronic	14 (28%)	27 (54%)	22 (44%)	15 (30%)
Mixed Cell Focus	5 (10%)	8 (16%)	14 (28%)	11 (22%)
Necrosis, Focal		5 (10%)	1 (2%)	3 (6%)
Vacuolization Cytoplasmic, Focal	8 (16%)	1 (2%)	6 (12%)	6 (12%)
Centrilobular, Cytomegaly, Diffuse			1 (2%)	
Centrilobular, Necrosis	1 (2%)		1 (2%)	
Mesentery	(11)	(6)	(4)	(9)
Inflammation, Chronic	1 (9%)			
Fat, Necrosis	10 (91%)	6 (100%)	3 (75%)	9 (100%)

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
TRIETHANOLAMINE

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
ALIMENTARY SYSTEM - CONT				
Lymphatic, Angiectasis	1 (9%)			
Oral Mucosa	(26)	(26)	(31)	(31)
Inflammation, Chronic	26 (100%)	26 (100%)	31 (100%)	31 (100%)
Pancreas	(50)	(50)	(50)	(50)
Acinus, Atrophy	1 (2%)	3 (6%)	1 (2%)	
Acinus, Hyperplasia		1 (2%)		
Duct, Cyst	1 (2%)	2 (4%)	1 (2%)	
Stomach, Forestomach	(50)	(50)	(50)	(50)
Inflammation, Chronic	1 (2%)			1 (2%)
Inflammation, Suppurative		1 (2%)		
Ulcer		1 (2%)	2 (4%)	
Epithelium, Cyst				1 (2%)
Epithelium, Hyperplasia, Focal		1 (2%)		1 (2%)
Epithelium, Mineralization			1 (2%)	
Stomach, Glandular	(50)	(50)	(50)	(50)
Inflammation, Acute			1 (2%)	
Ulcer		1 (2%)		1 (2%)
Epithelium, Cyst	1 (2%)		1 (2%)	
Epithelium, Hyperplasia, Focal	1 (2%)		1 (2%)	1 (2%)
Serosa, Inflammation, Chronic				1 (2%)
Tooth			(1)	
Inflammation, Chronic			1 (100%)	
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Aorta, Inflammation, Chronic			2 (4%)	
Aorta, Mineralization	1 (2%)	2 (4%)		
Heart	(50)	(50)	(50)	(50)
Artery, Inflammation, Chronic	3 (6%)	1 (2%)	2 (4%)	1 (2%)
Atrium, Thrombosis	2 (4%)			
Myocardium, Degeneration	4 (8%)		1 (2%)	
Myocardium, Inflammation, Acute	1 (2%)			
Myocardium, Inflammation, Chronic			1 (2%)	
Myocardium, Mineralization	1 (2%)	2 (4%)		
Myocardium, Necrosis			1 (2%)	
Pericardium, Inflammation, Chronic			1 (2%)	
Valve, Inflammation				1 (2%)
ENDOCRINE SYSTEM				

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

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
ENDOCRINE SYSTEM - CONT				
Adrenal Cortex	(50)	(50)	(50)	(50)
Hematopoietic Cell Proliferation	1 (2%)			
Hyperplasia, Focal	1 (2%)	1 (2%)		
Hypertrophy, Focal		2 (4%)	1 (2%)	1 (2%)
Inflammation, Suppurative			1 (2%)	
Subcapsular, Hyperplasia	49 (98%)	49 (98%)	50 (100%)	50 (100%)
Adrenal Medulla	(49)	(50)	(50)	(50)
Hyperplasia, Focal		1 (2%)	1 (2%)	
Infiltration Cellular, Histiocyte			1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	25 (50%)	18 (36%)	20 (40%)	18 (36%)
Parathyroid Gland	(39)	(41)	(45)	(46)
Cyst			1 (2%)	
Pituitary Gland	(50)	(50)	(50)	(50)
Angiectasis			1 (2%)	
Pars Distalis, Hyperplasia	11 (22%)	3 (6%)	9 (18%)	12 (24%)
Pars Intermedia, Hyperplasia		1 (2%)		
Thyroid Gland	(50)	(50)	(50)	(50)
Inflammation, Granulomatous	1 (2%)		1 (2%)	
C-Cell, Hyperplasia				2 (4%)
Follicle, Cyst	1 (2%)	1 (2%)	2 (4%)	1 (2%)
Follicular Cell, Necrosis	1 (2%)			
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(49)	(49)	(49)
Cyst	2 (4%)			1 (2%)
Inflammation, Suppurative	1 (2%)			
Ovary	(50)	(50)	(50)	(50)
Angiectasis	2 (4%)		2 (4%)	
Cyst	27 (54%)	22 (44%)	21 (42%)	25 (50%)
Mineralization				1 (2%)
Thrombosis		1 (2%)	3 (6%)	1 (2%)
Uterus	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)	2 (4%)	2 (4%)	2 (4%)
Thrombosis		1 (2%)	1 (2%)	
Endometrium, Hyperplasia, Cystic	49 (98%)	48 (96%)	47 (94%)	47 (94%)

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
TRIETHANOLAMINE

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Fibrosis			1 (2%)	
Myeloid Cell, Hyperplasia	1 (2%)			
Lymph Node	(6)	(7)	(4)	(6)
Deep Cervical, Hyperplasia, Lymphoid		1 (14%)		
Iliac, Hyperplasia, Lymphoid		1 (14%)	1 (25%)	
Lumbar, Hyperplasia, Lymphoid	1 (17%)		1 (25%)	
Lumbar, Inflammation, Acute	1 (17%)			
Mediastinal, Hyperplasia, Lymphoid	1 (17%)	1 (14%)		2 (33%)
Renal, Hyperplasia, Lymphoid				1 (17%)
Lymph Node, Mandibular	(49)	(50)	(50)	(50)
Hematopoietic Cell Proliferation		1 (2%)		
Hyperplasia, Lymphoid	1 (2%)		2 (4%)	
Lymph Node, Mesenteric	(50)	(49)	(48)	(48)
Hyperplasia, Histiocytic			1 (2%)	
Spleen	(50)	(50)	(49)	(50)
Atrophy	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Hematopoietic Cell Proliferation	32 (64%)	24 (48%)	30 (61%)	33 (66%)
Hyperplasia, Lymphoid			1 (2%)	
Thymus	(49)	(49)	(49)	(49)
Atrophy	13 (27%)	17 (35%)	19 (39%)	16 (33%)
Hyperplasia, Focal	1 (2%)			
Hyperplasia, Histiocytic	1 (2%)			
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Duct, Dilatation	1 (2%)		1 (2%)	
Skin	(50)	(50)	(50)	(50)
Epidermis, Hyperkeratosis	1 (2%)			
Epidermis, Hyperplasia	1 (2%)			
Epidermis, Inflammation, Suppurative	1 (2%)			
Epidermis, Ulcer	1 (2%)			
Site of Application - Epidermis, Hyperkeratosis	3 (6%)			
Site of Application - Epidermis, Hyperplasia	14 (28%)	50 (100%)	46 (92%)	50 (100%)
Site of Application - Epidermis, Inflammation, Suppurative	1 (2%)	2 (4%)	20 (40%)	32 (64%)
Site of Application - Epidermis, Ulcer	1 (2%)	1 (2%)	6 (12%)	17 (34%)
Subcutaneous Tissue, Edema		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)
TRIETHANOLAMINE

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
INTEGUMENTARY SYSTEM - CONT				
Subcutaneous Tissue, Fibrosis				1 (2%)
Subcutaneous Tissue, Inflammation, Chronic	1 (2%)			
Subcutaneous Tissue, Necrosis	1 (2%)			
Subcutaneous Tissue, Site of Application - Dermis, Inflammation, Chronic	4 (8%)	27 (54%)	31 (62%)	44 (88%)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Fibrosis	7 (14%)	6 (12%)	13 (26%)	10 (20%)
Fracture				1 (2%)
Hyperostosis		1 (2%)		
Cranium, Callus			1 (2%)	
Femur, Hyperostosis		1 (2%)		
NERVOUS SYSTEM				
Brain	(50)	(50)	(49)	(50)
Cyst Epithelial Inclusion				1 (2%)
Hydrocephalus			1 (2%)	
Artery, Inflammation, Chronic			1 (2%)	
Artery, Meninges, Inflammation, Chronic		1 (2%)		
Hypothalamus, Compression			3 (6%)	1 (2%)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Inflammation, Acute	1 (2%)			
Inflammation, Chronic	2 (4%)		3 (6%)	1 (2%)
Inflammation, Granulomatous	1 (2%)			
Mineralization		2 (4%)		
Alveolar Epithelium, Hyperplasia, Focal			1 (2%)	1 (2%)
Bronchus, Hyperplasia, Focal	1 (2%)			
Bronchus, Hyperplasia, Lymphoid	1 (2%)			
Mediastinum, Inflammation, Chronic			1 (2%)	
Serosa, Inflammation, Chronic			1 (2%)	
Nose	(50)	(50)	(50)	(50)
Inflammation, Chronic			1 (2%)	
Sinus, Inflammation, Suppurative				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)
TRIETHANOLAMINE

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
SPECIAL SENSES SYSTEM				
Eye	(49)	(50)	(50)	(50)
Degeneration	1 (2%)			
Inflammation, Chronic		1 (2%)		
Harderian Gland	(49)	(50)	(50)	(50)
Hyperplasia	4 (8%)	3 (6%)	4 (8%)	5 (10%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Hydronephrosis		1 (2%)		
Infarct	1 (2%)	5 (10%)	3 (6%)	3 (6%)
Metaplasia, Osseous			1 (2%)	3 (6%)
Nephropathy	24 (48%)	18 (36%)	23 (46%)	20 (40%)
Glomerulus, Amyloid Deposition		2 (4%)		
Glomerulus, Cyst				1 (2%)
Papilla, Necrosis	1 (2%)	1 (2%)		1 (2%)
Papilla, Renal Tubule, Atrophy				1 (2%)
Pelvis, Inflammation, Granulomatous			1 (2%)	
Renal Tubule, Cyst			1 (2%)	
Renal Tubule, Cytoplasmic Alteration		1 (2%)		
Renal Tubule, Mineralization				1 (2%)
Urinary Bladder	(50)	(50)	(49)	(49)
Cyst				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)
TRIETHANOLAMINE

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
DISPOSITION SUMMARY				
Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	5	2	6	8
Natural Death	8	5	10	2
Survivors				
Terminal Sacrifice	37	43	34	40
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Gallbladder	(48)	(49)	(50)	(47)
Necrosis	1 (2%)			
Intestine Large, Colon	(50)	(50)	(50)	(50)
Inflammation, Chronic			1 (2%)	
Goblet Cell, Hyperplasia			1 (2%)	
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Hemorrhage			1 (2%)	
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Epithelium, Hyperplasia	1 (2%)			
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Diverticulum	1 (2%)			
Epithelium, Hyperplasia		1 (2%)		
Peyer's Patch, Hyperplasia, Lymphoid	1 (2%)			1 (2%)
Serosa, Inflammation, Granulomatous		1 (2%)		
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Muscularis, Infiltration Cellular, Mononuclear Cell			1 (2%)	
Liver	(50)	(50)	(50)	(50)
Basophilic Focus	2 (4%)	6 (12%)	3 (6%)	2 (4%)
Clear Cell Focus	19 (38%)	23 (46%)	14 (28%)	11 (22%)
Eosinophilic Focus	9 (18%)	20 (40%)	31 (62%)	30 (60%)
Fibrosis		1 (2%)		
Hematopoietic Cell Proliferation	3 (6%)	4 (8%)	1 (2%)	2 (4%)
Hepatodiaphragmatic Nodule	1 (2%)		1 (2%)	
Infiltration Cellular, Lymphoid	3 (6%)	2 (4%)	2 (4%)	3 (6%)
Inflammation, Acute	1 (2%)			
Inflammation, Chronic	9 (18%)	14 (28%)	10 (20%)	11 (22%)
Mixed Cell Focus	13 (26%)	11 (22%)	15 (30%)	8 (16%)
Necrosis, Focal	4 (8%)	3 (6%)	7 (14%)	6 (12%)
Vacuolization Cytoplasmic, Focal	2 (4%)	1 (2%)	3 (6%)	5 (10%)

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
TRIETHANOLAMINE

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
ALIMENTARY SYSTEM - CONT				
Centrilobular, Necrosis		1 (2%)	1 (2%)	
Mesentery	(3)	(3)	(5)	(7)
Inflammation, Granulomatous			1 (20%)	
Artery, Inflammation, Chronic				1 (14%)
Fat, Necrosis	3 (100%)	3 (100%)	4 (80%)	5 (71%)
Oral Mucosa	(31)	(26)	(35)	(30)
Inflammation, Chronic	31 (100%)	26 (100%)	35 (100%)	30 (100%)
Pancreas	(50)	(50)	(50)	(50)
Acinus, Atrophy		1 (2%)		
Duct, Cyst				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Inflammation, Suppurative	1 (2%)			
Ulcer			1 (2%)	1 (2%)
Epithelium, Cyst				1 (2%)
Epithelium, Hyperplasia, Focal	3 (6%)		3 (6%)	2 (4%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Hyperplasia, Lymphoid				1 (2%)
Ulcer			2 (4%)	
Epithelium, Hyperplasia, Focal				1 (2%)
Glands, Ectasia		1 (2%)		
Tooth	(19)	(18)	(14)	(13)
Malformation	19 (100%)	18 (100%)	14 (100%)	13 (100%)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Aorta, Inflammation, Chronic				1 (2%)
Aorta, Mineralization		1 (2%)		
Pulmonary Vein, Thrombosis				1 (2%)
Heart	(50)	(50)	(50)	(50)
Infiltration Cellular, Mononuclear Cell	3 (6%)	1 (2%)		
Inflammation, Acute	1 (2%)			
Inflammation, Chronic				2 (4%)
Artery, Inflammation, Chronic		1 (2%)		3 (6%)
Atrium, Thrombosis	1 (2%)	1 (2%)		
Coronary Artery, Inflammation, Chronic				1 (2%)
Myocardium, Degeneration		1 (2%)		
Myocardium, Mineralization	1 (2%)		1 (2%)	2 (4%)
Valve, Inflammation, Chronic		1 (2%)		
Ventricle, Thrombosis	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)
TRIETHANOLAMINE

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Hyperplasia, Focal	8 (16%)	4 (8%)	3 (6%)	1 (2%)
Hypertrophy, Focal	16 (32%)	21 (42%)	10 (20%)	10 (20%)
Necrosis			1 (2%)	
Subcapsular, Hyperplasia	39 (78%)	45 (90%)	40 (80%)	40 (80%)
Zona Glomerulosa, Hyperplasia		2 (4%)	3 (6%)	1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia, Focal				2 (4%)
Necrosis			1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	45 (90%)	43 (86%)	43 (86%)	32 (64%)
Pituitary Gland	(50)	(49)	(49)	(50)
Pars Distalis, Hyperplasia	1 (2%)	2 (4%)		1 (2%)
Pars Intermedia, Hyperplasia	1 (2%)			3 (6%)
Thyroid Gland	(50)	(50)	(49)	(50)
Follicle, Cyst	1 (2%)	1 (2%)		1 (2%)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Coagulating Gland			(1)	(1)
Cyst			1 (100%)	
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm	1 (2%)		1 (2%)	2 (4%)
Inflammation, Chronic		1 (2%)		
Preputial Gland	(50)	(50)	(50)	(50)
Atrophy		1 (2%)		
Cyst	10 (20%)	14 (28%)	11 (22%)	15 (30%)
Inflammation, Chronic	1 (2%)			2 (4%)
Inflammation, Suppurative		1 (2%)		3 (6%)
Prostate	(50)	(50)	(50)	(50)
Hyperplasia		1 (2%)		
Seminal Vesicle	(50)	(50)	(50)	(50)
Atrophy				1 (2%)
Hyperplasia	1 (2%)	2 (4%)	2 (4%)	
Testes	(50)	(50)	(50)	(50)
Inflammation, Granulomatous				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)
TRIETHANOLAMINE

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
GENITAL SYSTEM - CONT				
Germinal Epithelium, Atrophy	4 (8%)	2 (4%)	1 (2%)	2 (4%)
Germinal Epithelium, Mineralization		2 (4%)	1 (2%)	
HEMATOPOIETIC SYSTEM				
Lymph Node, Mesenteric	(50)	(48)	(48)	(50)
Congestion			1 (2%)	
Hyperplasia, Lymphoid			1 (2%)	
Spleen	(49)	(50)	(50)	(50)
Atrophy	4 (8%)	1 (2%)		1 (2%)
Hematopoietic Cell Proliferation	14 (29%)	20 (40%)	17 (34%)	19 (38%)
Lymphoid Follicle, Hematopoietic Cell Proliferation	1 (2%)		1 (2%)	
Red Pulp, Infiltration Cellular, Mononuclear Cell	1 (2%)			
Thymus	(48)	(47)	(48)	(48)
Atrophy	38 (79%)	37 (79%)	37 (77%)	38 (79%)
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Dermis, Edema			1 (2%)	
Epidermis, Hyperkeratosis	1 (2%)			
Epidermis, Ulcer	1 (2%)			
Site of Application - Epidermis, Hyperkeratosis	3 (6%)			
Site of Application - Epidermis, Hyperplasia	5 (10%)	44 (88%)	45 (90%)	49 (98%)
Site of Application - Epidermis, Inflammation, Suppurative	1 (2%)	11 (22%)	33 (66%)	42 (84%)
Site of Application - Epidermis, Ulcer		3 (6%)	20 (40%)	47 (94%)
Subcutaneous Tissue, Site of Application - Dermis, Inflammation, Chronic	1 (2%)	15 (30%)	40 (80%)	49 (98%)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Fibrosis			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)
TRIETHANOLAMINE

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Compression				1 (2%)
Spinal Cord	(1)			
Necrosis	1 (100%)			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid			1 (2%)	
Inflammation, Acute		1 (2%)		
Inflammation, Chronic	1 (2%)			
Inflammation, Granulomatous	2 (4%)			
Alveolar Epithelium, Hyperplasia, Focal	2 (4%)	2 (4%)	1 (2%)	2 (4%)
Bronchus, Hyperplasia, Focal		1 (2%)		
Perivascular, Infiltration Cellular, Lymphoid				1 (2%)
Vein, Thrombosis				1 (2%)
Nose	(50)	(50)	(50)	(50)
Inflammation, Suppurative	2 (4%)		1 (2%)	
Polyp, Inflammatory		1 (2%)		
Respiratory Epithelium, Mineralization				1 (2%)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Degeneration	1 (2%)			
Cornea, Inflammation, Acute				1 (2%)
Retrobulbar, Inflammation, Suppurative	1 (2%)			
Harderian Gland	(50)	(50)	(49)	(50)
Hyperplasia	3 (6%)	5 (10%)	6 (12%)	7 (14%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Hydronephrosis		1 (2%)		
Infarct	2 (4%)	3 (6%)	2 (4%)	4 (8%)
Inflammation, Acute	2 (4%)			
Metaplasia, Osseous	1 (2%)	4 (8%)	2 (4%)	2 (4%)
Nephropathy	39 (78%)	42 (84%)	37 (74%)	40 (80%)
Artery, Thrombosis		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)
TRIETHANOLAMINE

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
URINARY SYSTEM - CONT				
Capsule, Inflammation, Chronic			1 (2%)	
Glomerulus, Cyst		2 (4%)		2 (4%)
Papilla, Necrosis			1 (2%)	
Renal Tubule, Cyst	4 (8%)	2 (4%)		4 (8%)
Renal Tubule, Hyperplasia		1 (2%)	1 (2%)	2 (4%)
Urinary Bladder	(50)	(50)	(50)	(50)
Cyst	1 (2%)			
Inflammation, Acute	1 (2%)			

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

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

FINAL #1/MICE

Facility: Battelle Columbus Laboratory

Chemical CAS #: 102-71-6

Lock Date: 05/31/01

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

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
DISPOSITION SUMMARY				
Animals Initially in Study	50	50	50	50
Early Deaths				
Natural Death	7	6	4	7
Moribund Sacrifice	8	10	5	10
Accidently Killed				1
Survivors				
Terminal Sacrifice	34	34	41	32
Natural Death	1			
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Large, Colon	(50)	(50)	(50)	(50)
Leiomyoma				1 (2%)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Leiomyosarcoma, Metastatic, Uterus				1 (2%)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Carcinoma		1 (2%)		
Polyp Adenomatous			1 (2%)	
Liver	(50)	(50)	(50)	(50)
Hemangioma	1 (2%)			
Hemangiosarcoma		1 (2%)		
Hepatocellular Carcinoma	5 (10%)	8 (16%)	4 (8%)	5 (10%)
Hepatocellular Carcinoma, Multiple	1 (2%)			
Hepatocellular Adenoma	9 (18%)	15 (30%)	13 (26%)	16 (32%)
Hepatocellular Adenoma, Multiple		3 (6%)	7 (14%)	17 (34%)
Histiocytic Sarcoma	4 (8%)	5 (10%)		3 (6%)
Mesentery	(11)	(6)	(4)	(9)
Liposarcoma			1 (25%)	
Oral Mucosa	(26)	(26)	(31)	(31)
Histiocytic Sarcoma	1 (4%)			
Pancreas	(50)	(50)	(50)	(50)
Histiocytic Sarcoma		1 (2%)		
Salivary Glands	(50)	(50)	(50)	(50)
Carcinoma				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma	2 (4%)		2 (4%)	4 (8%)
Squamous Cell Papilloma, Multiple			1 (2%)	

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
ALIMENTARY SYSTEM - cont				
Stomach, Glandular	(50)	(50)	(50)	(50)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)			
Histiocytic Sarcoma	1 (2%)	2 (4%)		1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Carcinoma		1 (2%)		
Histiocytic Sarcoma		1 (2%)		
Subcapsular, Adenoma				1 (2%)
Adrenal Medulla	(49)	(50)	(50)	(50)
Pheochromocytoma Benign	1 (2%)		1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma		1 (2%)	1 (2%)	1 (2%)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	8 (16%)	5 (10%)	5 (10%)	5 (10%)
Pars Distalis, Carcinoma				1 (2%)
Pars Intermedia, Adenoma		3 (6%)	1 (2%)	
Thyroid Gland	(50)	(50)	(50)	(50)
Follicle, Adenoma			1 (2%)	3 (6%)
Follicle, Carcinoma	1 (2%)			
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Ovary	(50)	(50)	(50)	(50)
Cystadenoma	1 (2%)	1 (2%)		1 (2%)
Granulosa Cell Tumor Malignant				1 (2%)
Histiocytic Sarcoma	2 (4%)	2 (4%)		1 (2%)
Luteoma	1 (2%)	1 (2%)		
Teratoma Benign				1 (2%)
Tubulostromal Adenoma				1 (2%)

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
GENITAL SYSTEM - cont				
Uterus	(50)	(50)	(50)	(50)
Histiocytic Sarcoma	3 (6%)	3 (6%)		1 (2%)
Leiomyosarcoma		1 (2%)		2 (4%)
Polyp Stromal	1 (2%)		3 (6%)	1 (2%)
Vagina				(1)
Leiomyosarcoma, Metastatic, Uterus				1 (100%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Histiocytic Sarcoma	1 (2%)	1 (2%)		1 (2%)
Lymph Node	(6)	(7)	(4)	(6)
Iliac, Histiocytic Sarcoma		1 (14%)		
Lumbar, Histiocytic Sarcoma	1 (17%)			
Mediastinal, Liposarcoma, Metastatic, Mesentery			1 (25%)	
Renal, Histiocytic Sarcoma		1 (14%)		
Lymph Node, Mandibular	(49)	(50)	(50)	(50)
Histiocytic Sarcoma		1 (2%)		
Lymph Node, Mesenteric	(50)	(49)	(48)	(48)
Histiocytic Sarcoma		3 (6%)		
Spleen	(50)	(50)	(49)	(50)
Hemangiosarcoma	1 (2%)		1 (2%)	1 (2%)
Histiocytic Sarcoma	2 (4%)	3 (6%)		
Thymus	(49)	(49)	(49)	(49)
Histiocytic Sarcoma		1 (2%)		
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Sebaceous Gland, Adenoma	1 (2%)			
Subcutaneous Tissue, Fibrosarcoma	1 (2%)	1 (2%)	2 (4%)	1 (2%)
Subcutaneous Tissue, Hemangiosarcoma				1 (2%)
Subcutaneous Tissue, Hemangiosarcoma, Multiple	1 (2%)			
Subcutaneous Tissue, Histiocytic Sarcoma	1 (2%)			1 (2%)
Subcutaneous Tissue, Melanoma Malignant, Multiple	1 (2%)			
Subcutaneous Tissue, Osteosarcoma	1 (2%)			
Subcutaneous Tissue, Site of Application - Dermis, Lymphoma Malignant			1 (2%)	

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Osteosarcoma		1 (2%)		
Skeletal Muscle	(1)	(2)	(1)	(3)
Hemangiosarcoma, Metastatic, Spleen			1 (100%)	
Rhabdomyosarcoma	1 (100%)	2 (100%)		2 (67%)
NERVOUS SYSTEM				
Brain	(50)	(50)	(49)	(50)
Histiocytic Sarcoma	1 (2%)			1 (2%)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	3 (6%)	1 (2%)	2 (4%)	1 (2%)
Alveolar/Bronchiolar Carcinoma	2 (4%)	2 (4%)	3 (6%)	1 (2%)
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Hemangiosarcoma, Metastatic, Heart	1 (2%)			
Hepatocellular Carcinoma, Metastatic, Liver	3 (6%)	3 (6%)		2 (4%)
Histiocytic Sarcoma	4 (8%)	4 (8%)		1 (2%)
Liposarcoma, Metastatic, Mesentery			1 (2%)	
Osteosarcoma, Metastatic, Bone		1 (2%)		
Osteosarcoma, Metastatic, Skin	1 (2%)			
Nose	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Eye	(49)	(50)	(50)	(50)
Harderian Gland	(49)	(50)	(50)	(50)
Adenoma	5 (10%)	5 (10%)	3 (6%)	3 (6%)
Carcinoma	2 (4%)			

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Histiocytic Sarcoma	2 (4%)	3 (6%)		
Renal Tubule, Adenoma				1 (2%)
Urinary Bladder	(50)	(50)	(49)	(49)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	4 (8%)	5 (10%)		3 (6%)
Lymphoma Malignant	8 (16%)	9 (18%)	6 (12%)	8 (16%)

* Number of animals with any tissue examined microscopically

MICE:B6C3F1 FEMALE	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
TUMOR SUMMARY				
Total Animals with Primary Neoplasms (b)	38	41	35	44
Total Primary Neoplasms	63	67	58	84
Total Animals with Benign Neoplasms	24	28	27	38
Total Benign Neoplasms	33	35	41	57
Total Animals with Malignant Neoplasms	27	26	16	21
Total Malignant Neoplasms	30	32	17	27
Total Animals with Metastatic Neoplasms	6	4	2	3
Total Metastatic Neoplasm	6	4	3	4
Total Animals with Malignant Neoplasms Uncertain Primary Site				
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

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
DISPOSITION SUMMARY				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	5	2	6	8
Natural Death	8	5	10	2
Survivors				
Terminal Sacrifice	37	43	34	40
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Adenoma				1 (2%)
Carcinoma	2 (4%)	1 (2%)		1 (2%)
Carcinoma, Multiple	1 (2%)			
Sarcoma, Metastatic, Adrenal Medulla		1 (2%)		
Liver	(50)	(50)	(50)	(50)
Hemangioma		1 (2%)		2 (4%)
Hemangiosarcoma	1 (2%)		4 (8%)	1 (2%)
Hemangiosarcoma, Multiple			2 (4%)	
Hemangiosarcoma, Metastatic, Blood Vessel				1 (2%)
Hemangiosarcoma, Metastatic, Spleen	1 (2%)	1 (2%)	1 (2%)	
Hepatoblastoma	1 (2%)	1 (2%)	2 (4%)	3 (6%)
Hepatocellular Carcinoma	11 (22%)	10 (20%)	13 (26%)	10 (20%)
Hepatocellular Carcinoma, Multiple	6 (12%)	4 (8%)	1 (2%)	1 (2%)
Hepatocellular Adenoma	13 (26%)	14 (28%)	12 (24%)	15 (30%)
Hepatocellular Adenoma, Multiple	6 (12%)	4 (8%)	11 (22%)	5 (10%)
Hepatocholangiocarcinoma				1 (2%)
Histiocytic Sarcoma		1 (2%)		2 (4%)
Sarcoma, Metastatic, Adrenal Medulla		1 (2%)		
Mesentery	(3)	(3)	(5)	(7)
Fibrous Histiocytoma				1 (14%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma	1 (2%)	2 (4%)		1 (2%)
Tongue				(1)
Squamous Cell Carcinoma				1 (100%)
Tooth	(19)	(18)	(14)	(13)
Odontoma	1 (5%)			

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Aorta, Hemangiosarcoma				1 (2%)
Heart	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Kidney				1 (2%)
Fibrous Histiocytoma, Metastatic, Mesentery				1 (2%)
Histiocytic Sarcoma				1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (2%)	
Subcapsular, Adenoma	3 (6%)	3 (6%)	6 (12%)	5 (10%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	1 (2%)			1 (2%)
Sarcoma		1 (2%)		
Pituitary Gland	(50)	(49)	(49)	(50)
Pars Distalis, Adenoma			1 (2%)	
Pars Intermedia, Adenoma	1 (2%)			1 (2%)
Thyroid Gland	(50)	(50)	(49)	(50)
Follicle, Adenoma	1 (2%)		1 (2%)	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Mesentery				1 (2%)
Testes	(50)	(50)	(50)	(50)
Interstitial Cell, Adenoma		1 (2%)		

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hemangiosarcoma, Metastatic, Spleen	1 (2%)		1 (2%)	
Histiocytic Sarcoma				1 (2%)
Lymph Node	(1)		(1)	(1)
Mediastinal, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (100%)			
Mediastinal, Fibrous Histiocytoma, Metastatic, Mesentery				1 (100%)
Mediastinal, Hepatocellular Carcinoma, Metastatic, Liver			1 (100%)	
Pancreatic, Fibrous Histiocytoma, Metastatic, Mesentery				1 (100%)
Renal, Fibrous Histiocytoma				1 (100%)
Lymph Node, Mesenteric	(50)	(48)	(48)	(50)
Histiocytic Sarcoma				1 (2%)
Spleen	(49)	(50)	(50)	(50)
Hemangioma	1 (2%)			
Hemangiosarcoma	2 (4%)	2 (4%)	2 (4%)	
Histiocytic Sarcoma		1 (2%)		1 (2%)
Thymus	(48)	(47)	(48)	(48)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (2%)	
Carcinoma, Metastatic, Kidney				1 (2%)
Fibrous Histiocytoma, Metastatic, Mesentery				1 (2%)
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma				1 (2%)
Subcutaneous Tissue, Hibernoma				1 (2%)
Subcutaneous Tissue, Melanoma Malignant	1 (2%)			
Subcutaneous Tissue, Skin, Site of Application, Hemangiosarcoma			1 (2%)	
Subcutaneous Tissue, Site of Application - Dermis, Mast Cell Tumor Benign		1 (2%)		

INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)
TRIETHANOLAMINE

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Osteosarcoma	1 (2%)			
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	6 (12%)	6 (12%)	11 (22%)	7 (14%)
Alveolar/Bronchiolar Adenoma, Multiple		1 (2%)	1 (2%)	2 (4%)
Alveolar/Bronchiolar Carcinoma	6 (12%)	6 (12%)	8 (16%)	3 (6%)
Alveolar/Bronchiolar Carcinoma, Multiple	1 (2%)			1 (2%)
Carcinoma, Metastatic, Harderian Gland		1 (2%)		
Carcinoma, Metastatic, Kidney				1 (2%)
Fibrous Histiocytoma, Metastatic, Mesentery				1 (2%)
Hepatoblastoma, Metastatic, Liver			1 (2%)	1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver	8 (16%)	6 (12%)	6 (12%)	2 (4%)
Hepatocholangiocarcinoma, Metastatic, Liver				1 (2%)
Histiocytic Sarcoma		1 (2%)		2 (4%)
SPECIAL SENSES SYSTEM				
Harderian Gland	(50)	(50)	(49)	(50)
Adenoma	6 (12%)	2 (4%)	2 (4%)	5 (10%)
Carcinoma		1 (2%)		1 (2%)
Bilateral, Adenoma	1 (2%)			1 (2%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Histiocytic Sarcoma		1 (2%)		1 (2%)
Renal Tubule, Adenoma	1 (2%)		1 (2%)	1 (2%)

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
URINARY SYSTEM - cont				
Renal Tubule, Carcinoma, Multiple				1 (2%)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)		2 (4%)
Lymphoma Malignant			1 (2%)	1 (2%)

* Number of animals with any tissue examined microscopically

MICE:B6C3F1 MALE	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG
TUMOR SUMMARY				
Total Animals with Primary Neoplasms (b)	45	35	43	41
Total Primary Neoplasms	75	62	80	79
Total Animals with Benign Neoplasms	30	25	32	32
Total Benign Neoplasms	42	35	46	48
Total Animals with Malignant Neoplasms	28	24	27	21
Total Malignant Neoplasms	33	27	34	31
Total Animals with Metastatic Neoplasms	10	8	9	6
Total Metastatic Neoplasm	11	10	12	14
Total Animals with Malignant Neoplasms Uncertain Primary Site				
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 #1/MICE

REASONS FOR REMOVAL: ALL

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS: INCLUDE ALL

NTP
LAB: Battelle Columbus
EXPERIMENT: 05109 TEST: 14
TEST TYPE: CHRONIC
CONT: N01-ES-85427
PATHOLOGIST: MISSING
Mice(B6C3F1)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TRIETHANOLAMINE

CAGES FROM 0000 TO LAST CAGE
ROUTE: SKIN APPLICATION

REPORT: PEIRPT08
DATE: 06/06/02
TIME: 08:39:59

NTP C#: 61621E
CAS: 102-71-6

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
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Ovary
Pituitary Gland
Salivary Glands
Spleen
Testes
Thyroid Gland

NTP
LAB: Battelle Columbus
EXPERIMENT: 05109 TEST: 14
TEST TYPE: CHRONIC
CONT: N01-ES-85427
PATHOLOGIST: MISSING

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TRIETHANOLAMINE

CAGES FROM 0000 TO LAST CAGE
ROUTE: SKIN APPLICATION

REPORT: PEIRPT08
DATE: 06/06/02
TIME: 08:39:59

NTP C#: 61621E
CAS: 102-71-6

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TRIETHANOLAMINE

Male Mice

Organ	Morphology
Liver	Hemangiosarcoma
All Organs	Hemangiosarcoma
	Benign Tumors
	Malignant and Benign Tumors

Female Mice

Organ	Morphology
Liver	Hepatocellular Adenoma
	Hepatocellular Carcinoma or Hepatocellular Adenoma
	Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma
Thyroid Gland: Follicular Cell	Adenoma
All Organs	Benign Tumors
	Malignant Tumors

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Intestine Small: Jejunum Carcinoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/47.21	1/46.90	0/43.35	1/46.04	0/44.21	1/43.59	0/44.71	0/44.29
POLY-3 PERCENT (g)	6.4%	2.1%	0.0%	2.2%	0.0%	2.3%	0.0%	0.0%
TERMINAL (d)	3/37 (8%)	1/43 (2%)	0/34 (0%)	1/40 (3%)	0/35 (0%)	1/34 (3%)	0/41 (0%)	0/32 (0%)
FIRST INCIDENCE	726 (T)	726 (T)	---	726 (T)	---	729 (T)	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.347N	P=0.253N	P=0.136N	P=0.278N	P=0.619N	P=0.494	(e)	(e)
POLY 3	P=0.352N	P=0.308N	P=0.135N	P=0.314N	P=0.603N	P=0.497	(e)	(e)
POLY 1.5	P=0.351N	P=0.309N	P=0.129N	P=0.311N	P=0.603N	P=0.497	(e)	(e)
POLY 6	P=0.354N	P=0.304N	P=0.141N	P=0.317N	P=0.604N	P=0.498	(e)	(e)
LOGISTIC REGRESSION	P=0.347N	P=0.253N	(e)	P=0.278N	(e)	P=0.494	(e)	(e)
COCH-ARM / FISHERS	P=0.352N	P=0.309N	P=0.121N	P=0.309N	P=0.601N	P=0.500	(e)	(e)

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Intestine Small: Site Unspecified Carcinoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/47.21	1/46.90	0/43.35	1/46.04	0/44.21	1/43.59	0/44.71	0/44.29
POLY-3 PERCENT (g)	6.4%	2.1%	0.0%	2.2%	0.0%	2.3%	0.0%	0.0%
TERMINAL (d)	3/37 (8%)	1/43 (2%)	0/34 (0%)	1/40 (3%)	0/35 (0%)	1/34 (3%)	0/41 (0%)	0/32 (0%)
FIRST INCIDENCE	726 (T)	726 (T)	---	726 (T)	---	729 (T)	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.347N	P=0.253N	P=0.136N	P=0.278N	P=0.619N	P=0.494	(e)	(e)
POLY 3	P=0.352N	P=0.308N	P=0.135N	P=0.314N	P=0.603N	P=0.497	(e)	(e)
POLY 1.5	P=0.351N	P=0.309N	P=0.129N	P=0.311N	P=0.603N	P=0.497	(e)	(e)
POLY 6	P=0.354N	P=0.304N	P=0.141N	P=0.317N	P=0.604N	P=0.498	(e)	(e)
LOGISTIC REGRESSION	P=0.347N	P=0.253N	(e)	P=0.278N	(e)	P=0.494	(e)	(e)
COCH-ARM / FISHERS	P=0.352N	P=0.309N	P=0.121N	P=0.309N	P=0.601N	P=0.500	(e)	(e)

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

	Males				Females			
Dose	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Intestine Small: Site Unspecified Carcinoma or Adenoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/47.21	1/46.90	0/43.35	2/46.88	0/44.21	1/43.59	0/44.71	0/44.29
POLY-3 PERCENT (g)	6.4%	2.1%	0.0%	4.3%	0.0%	2.3%	0.0%	0.0%
TERMINAL (d)	3/37 (8%)	1/43 (2%)	0/34 (0%)	1/40 (3%)	0/35 (0%)	1/34 (3%)	0/41 (0%)	0/32 (0%)
FIRST INCIDENCE	726 (T)	726 (T)	---	399	---	729 (T)	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.624N	P=0.253N	P=0.136N	P=0.472N	P=0.619N	P=0.494	(e)	(e)
POLY 3	P=0.629N	P=0.308N	P=0.135N	P=0.503N	P=0.603N	P=0.497	(e)	(e)
POLY 1.5	P=0.630N	P=0.309N	P=0.129N	P=0.502N	P=0.603N	P=0.497	(e)	(e)
POLY 6	P=0.631N	P=0.304N	P=0.141N	P=0.504N	P=0.604N	P=0.498	(e)	(e)
LOGISTIC REGRESSION	P=0.625N	P=0.253N	(e)	P=0.419N	(e)	P=0.494	(e)	(e)
COCH-ARM / FISHERS	P=0.633N	P=0.309N	P=0.121N	P=0.500N	P=0.601N	P=0.500	(e)	(e)

	Males				Females			
Dose	0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Kidney: Renal Tubule Carcinoma or Adenoma								
TUMOR RATES								
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/47.21	0/46.90	1/43.35	2/46.21	0/44.21	0/43.59	0/44.71	1/44.29
POLY-3 PERCENT (g)	2.1%	0.0%	2.3%	4.3%	0.0%	0.0%	0.0%	2.3%
TERMINAL (d)	1/37 (3%)	0/43 (0%)	1/34 (3%)	1/40 (3%)	0/35 (0%)	0/34 (0%)	0/41 (0%)	1/32 (3%)
FIRST INCIDENCE	726 (T)	---	726 (T)	683	---	---	---	729 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.242	P=0.470N	P=0.743	P=0.513	P=0.201	(e)	(e)	P=0.482
POLY 3	P=0.232	P=0.501N	P=0.741	P=0.493	P=0.222	(e)	(e)	P=0.500
POLY 1.5	P=0.234	P=0.502N	P=0.748	P=0.495	P=0.221	(e)	(e)	P=0.499
POLY 6	P=0.229	P=0.499N	P=0.734	P=0.491	P=0.223	(e)	(e)	P=0.502
LOGISTIC REGRESSION	P=0.231	(e)	P=0.743	P=0.494	(e)	(e)	(e)	P=0.482
COCH-ARM / FISHERS	P=0.235	P=0.500N	P=0.753N	P=0.500	P=0.221	(e)	(e)	P=0.500

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Liver Hepatocellular Carcinoma								
TUMOR RATES								
OVERALL (a)	17/50 (34%)	14/50 (28%)	14/50 (28%)	11/50 (22%)	6/50 (12%)	8/50 (16%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	17/49.44	14/48.17	14/47.23	11/46.72	6/45.00	8/44.74	4/45.19	5/44.40
POLY-3 PERCENT (g)	34.4%	29.1%	29.6%	23.6%	13.3%	17.9%	8.9%	11.3%
TERMINAL (d)	8/37 (22%)	11/43 (26%)	5/34 (15%)	9/40 (23%)	3/35 (9%)	4/34 (12%)	3/41 (7%)	4/32 (13%)
FIRST INCIDENCE	511	554	439	572	595	601	586	701
STATISTICAL TESTS								
LIFE TABLE	P=0.167N	P=0.254N	P=0.469N	P=0.136N	P=0.386N	P=0.377	P=0.315N	P=0.537N
POLY 3	P=0.177N	P=0.365N	P=0.390N	P=0.172N	P=0.354N	P=0.382	P=0.367N	P=0.509N
POLY 1.5	P=0.162N	P=0.357N	P=0.367N	P=0.156N	P=0.352N	P=0.378	P=0.375N	P=0.509N
POLY 6	P=0.200N	P=0.368N	P=0.418N	P=0.193N	P=0.359N	P=0.390	P=0.350N	P=0.511N
LOGISTIC REGRESSION	P=0.121N	P=0.303N	P=0.118N	P=0.110N	P=0.345N	P=0.384	P=0.371N	P=0.501N
COCH-ARM / FISHERS	P=0.142N	P=0.333N	P=0.333N	P=0.133N	P=0.346N	P=0.387	P=0.370N	P=0.500N

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Liver Hepatocellular Carcinoma or Hepatoblastoma								
TUMOR RATES								
OVERALL (a)	18/50 (36%)	15/50 (30%)	15/50 (30%)	13/50 (26%)	6/50 (12%)	8/50 (16%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	18/49.44	15/48.17	15/47.23	13/47.10	6/45.00	8/44.74	4/45.19	5/44.40
POLY-3 PERCENT (g)	36.4%	31.1%	31.8%	27.6%	13.3%	17.9%	8.9%	11.3%
TERMINAL (d)	9/37 (24%)	12/43 (28%)	6/34 (18%)	10/40 (25%)	3/35 (9%)	4/34 (12%)	3/41 (7%)	4/32 (13%)
FIRST INCIDENCE	511	554	439	572	595	601	586	701
STATISTICAL TESTS								
LIFE TABLE	P=0.238N	P=0.249N	P=0.476N	P=0.192N	P=0.386N	P=0.377	P=0.315N	P=0.537N
POLY 3	P=0.253N	P=0.369N	P=0.395N	P=0.240N	P=0.354N	P=0.382	P=0.367N	P=0.509N
POLY 1.5	P=0.237N	P=0.360N	P=0.371N	P=0.222N	P=0.352N	P=0.378	P=0.375N	P=0.509N
POLY 6	P=0.276N	P=0.373N	P=0.425N	P=0.261N	P=0.359N	P=0.390	P=0.350N	P=0.511N
LOGISTIC REGRESSION	P=0.190N	P=0.308N	P=0.133N	P=0.161N	P=0.345N	P=0.384	P=0.371N	P=0.501N
COCH-ARM / FISHERS	P=0.214N	P=0.335N	P=0.335N	P=0.194N	P=0.346N	P=0.387	P=0.370N	P=0.500N

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Liver Hepatocellular Carcinoma or Hepatocellular Adenoma								
TUMOR RATES								
OVERALL (a)	33/50 (66%)	27/50 (54%)	33/50 (66%)	25/50 (50%)	12/50 (24%)	23/50 (46%)	24/50 (48%)	34/50 (68%)
POLY-3 RATE (b)	33/49.59	27/48.17	33/47.69	25/47.46	12/45.63	23/45.10	24/46.46	34/45.59
POLY-3 PERCENT (g)	66.6%	56.1%	69.2%	52.7%	26.3%	51.0%	51.7%	74.6%
TERMINAL (d)	23/37 (62%)	24/43 (56%)	22/34 (65%)	21/40 (53%)	7/35 (20%)	17/34 (50%)	21/41 (51%)	26/32 (81%)
FIRST INCIDENCE	511	554	439	572	595	601	444	604
STATISTICAL TESTS								
LIFE TABLE	P=0.138N	P=0.067N	P=0.365	P=0.072N	P<0.001 **	P=0.023 *	P=0.042 *	P<0.001 **
POLY 3	P=0.148N	P=0.195N	P=0.475	P=0.116N	P<0.001 **	P=0.011 *	P=0.009 **	P<0.001 **
POLY 1.5	P=0.130N	P=0.183N	P=0.518	P=0.099N	P<0.001 **	P=0.012 *	P=0.008 **	P<0.001 **
POLY 6	P=0.173N	P=0.203N	P=0.425	P=0.136N	P<0.001 **	P=0.012 *	P=0.012 *	P<0.001 **
LOGISTIC REGRESSION	P=0.114N	P=0.155N	P=0.544N	P=0.081N	P<0.001 **	P=0.015 *	P=0.010 *	P<0.001 **
COCH-ARM / FISHERS	P=0.112N	P=0.154N	P=0.583N	P=0.078N	P<0.001 **	P=0.018 *	P=0.011 *	P<0.001 **

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Liver Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma								
TUMOR RATES								
OVERALL (a)	33/50 (66%)	27/50 (54%)	34/50 (68%)	26/50 (52%)	12/50 (24%)	23/50 (46%)	24/50 (48%)	34/50 (68%)
POLY-3 RATE (b)	33/49.59	27/48.17	34/47.69	26/47.46	12/45.63	23/45.10	24/46.46	34/45.59
POLY-3 PERCENT (g)	66.6%	56.1%	71.3%	54.8%	26.3%	51.0%	51.7%	74.6%
TERMINAL (d)	23/37 (62%)	24/43 (56%)	23/34 (68%)	22/40 (55%)	7/35 (20%)	17/34 (50%)	21/41 (51%)	26/32 (81%)
FIRST INCIDENCE	511	554	439	572	595	601	444	604
STATISTICAL TESTS								
LIFE TABLE	P=0.183N	P=0.067N	P=0.303	P=0.097N	P<0.001 **	P=0.023 *	P=0.042 *	P<0.001 **
POLY 3	P=0.208N	P=0.195N	P=0.386	P=0.162N	P<0.001 **	P=0.011 *	P=0.009 **	P<0.001 **
POLY 1.5	P=0.185N	P=0.183N	P=0.431	P=0.141N	P<0.001 **	P=0.012 *	P=0.008 **	P<0.001 **
POLY 6	P=0.240N	P=0.203N	P=0.337	P=0.189N	P<0.001 **	P=0.012 *	P=0.012 *	P<0.001 **
LOGISTIC REGRESSION	P=0.163N	P=0.155N	P=0.534	P=0.117N	P<0.001 **	P=0.015 *	P=0.010 *	P<0.001 **
COCH-ARM / FISHERS	P=0.159N	P=0.154N	P=0.500	P=0.111N	P<0.001 **	P=0.018 *	P=0.011 *	P<0.001 **

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Lung Alveolar/Bronchiolar Adenoma								
TUMOR RATES								
OVERALL (a)	6/50 (12%)	7/50 (14%)	12/50 (24%)	9/50 (18%)	3/50 (6%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	6/47.21	7/46.90	12/44.82	9/46.04	3/44.21	1/43.59	2/44.71	1/44.29
POLY-3 PERCENT (g)	12.7%	14.9%	26.8%	19.6%	6.8%	2.3%	4.5%	2.3%
TERMINAL (d)	6/37 (16%)	7/43 (16%)	7/34 (21%)	9/40 (23%)	3/35 (9%)	1/34 (3%)	2/41 (5%)	1/32 (3%)
FIRST INCIDENCE	726 (T)	726 (T)	487	726 (T)	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.312	P=0.616	P=0.071	P=0.343	P=0.378N	P=0.315N	P=0.428N	P=0.337N
POLY 3	P=0.272	P=0.495	P=0.074	P=0.269	P=0.344N	P=0.310N	P=0.495N	P=0.304N
POLY 1.5	P=0.282	P=0.494	P=0.081	P=0.276	P=0.345N	P=0.311N	P=0.502N	P=0.307N
POLY 6	P=0.260	P=0.503	P=0.069	P=0.264	P=0.343N	P=0.308N	P=0.480N	P=0.301N
LOGISTIC REGRESSION	P=0.281	P=0.616	P=0.082	P=0.343	P=0.378N	P=0.315N	P=0.428N	P=0.337N
COCH-ARM / FISHERS	P=0.296	P=0.500	P=0.096	P=0.288	P=0.347N	P=0.309N	P=0.500N	P=0.309N

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Lung Alveolar/Bronchiolar Carcinoma								
TUMOR RATES								
OVERALL (a)	7/50 (14%)	6/50 (12%)	8/50 (16%)	4/50 (8%)	2/50 (4%)	2/50 (4%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	7/48.09	6/46.90	8/44.97	4/46.04	2/44.21	2/43.59	3/44.71	1/44.29
POLY-3 PERCENT (g)	14.6%	12.8%	17.8%	8.7%	4.5%	4.6%	6.7%	2.3%
TERMINAL (d)	5/37 (14%)	6/43 (14%)	5/34 (15%)	4/40 (10%)	2/35 (6%)	2/34 (6%)	3/41 (7%)	1/32 (3%)
FIRST INCIDENCE	511	726 (T)	503	726 (T)	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.222N	P=0.408N	P=0.425	P=0.233N	P=0.409N	P=0.685	P=0.572	P=0.531N
POLY 3	P=0.246N	P=0.519N	P=0.444	P=0.287N	P=0.370N	P=0.689	P=0.505	P=0.499N
POLY 1.5	P=0.237N	P=0.515N	P=0.464	P=0.278N	P=0.373N	P=0.688	P=0.498	P=0.502N
POLY 6	P=0.257N	P=0.518N	P=0.427	P=0.296N	P=0.368N	P=0.691	P=0.520	P=0.496N
LOGISTIC REGRESSION	P=0.220N	P=0.496N	P=0.609N	P=0.251N	P=0.409N	P=0.685	P=0.572	P=0.531N
COCH-ARM / FISHERS	P=0.225N	P=0.500N	P=0.500	P=0.262N	P=0.373N	P=0.691N	P=0.500	P=0.500N

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Lung Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma								
TUMOR RATES								
OVERALL (a)	12/50 (24%)	13/50 (26%)	19/50 (38%)	13/50 (26%)	5/50 (10%)	3/50 (6%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	12/48.09	13/46.90	19/46.44	13/46.04	5/44.21	3/43.59	4/44.71	2/44.29
POLY-3 PERCENT (g)	25.0%	27.7%	40.9%	28.2%	11.3%	6.9%	9.0%	4.5%
TERMINAL (d)	10/37 (27%)	13/43 (30%)	11/34 (32%)	13/40 (33%)	5/35 (14%)	3/34 (9%)	4/41 (10%)	2/32 (6%)
FIRST INCIDENCE	511	726 (T)	487	726 (T)	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.552N	P=0.528N	P=0.068	P=0.579	P=0.262N	P=0.371N	P=0.401N	P=0.252N
POLY 3	P=0.481	P=0.471	P=0.074	P=0.450	P=0.224N	P=0.364N	P=0.493N	P=0.215N
POLY 1.5	P=0.504	P=0.478	P=0.080	P=0.468	P=0.227N	P=0.365N	P=0.503N	P=0.218N
POLY 6	P=0.454	P=0.472	P=0.072	P=0.431	P=0.222N	P=0.360N	P=0.472N	P=0.211N
LOGISTIC REGRESSION	P=0.528	P=0.492	P=0.131	P=0.471	P=0.262N	P=0.371N	P=0.401N	P=0.252N
COCH-ARM / FISHERS	P=0.535	P=0.500	P=0.097	P=0.500	P=0.228N	P=0.357N	P=0.500N	P=0.218N

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma								
TUMOR RATES								
OVERALL (a)	0/50 (0%)	0/49 (0%)	1/49 (2%)	0/50 (0%)	8/50 (16%)	5/50 (10%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	0/47.21	0/46.22	1/42.35	0/46.04	8/44.88	5/43.59	5/44.71	5/44.29
POLY-3 PERCENT (g)	0.0%	0.0%	2.4%	0.0%	17.8%	11.5%	11.2%	11.3%
TERMINAL (d)	0/37 (0%)	0/43 (0%)	1/33 (3%)	0/40 (0%)	6/35 (17%)	5/34 (15%)	5/41 (12%)	5/32 (16%)
FIRST INCIDENCE	---	---	726 (T)	---	619	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.775N	(e)	P=0.477	(e)	P=0.406N	P=0.291N	P=0.198N	P=0.327N
POLY 3	P=0.784N	(e)	P=0.478	(e)	P=0.344N	P=0.294N	P=0.277N	P=0.283N
POLY 1.5	P=0.782N	(e)	P=0.485	(e)	P=0.345N	P=0.291N	P=0.284N	P=0.284N
POLY 6	P=0.786N	(e)	P=0.472	(e)	P=0.345N	P=0.297N	P=0.263N	P=0.284N
LOGISTIC REGRESSION	(e)	(e)	P=0.477	(e)	P=0.335N	P=0.281N	P=0.263N	P=0.271N
COCH-ARM / FISHERS	P=0.780N	(e)	P=0.495	(e)	P=0.346N	P=0.277N	P=0.277N	P=0.277N

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Spleen Hemangiosarcoma								
TUMOR RATES								
OVERALL (a)	2/49 (4%)	2/50 (4%)	2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/46.88	2/46.90	2/43.60	0/46.04	1/44.21	0/43.59	1/44.71	1/44.29
POLY-3 PERCENT (g)	4.3%	4.3%	4.6%	0.0%	2.3%	0.0%	2.2%	2.3%
TERMINAL (d)	0/37 (0%)	2/43 (5%)	1/34 (3%)	0/40 (0%)	1/35 (3%)	0/34 (0%)	1/41 (2%)	1/32 (3%)
FIRST INCIDENCE	624	726 (T)	659	---	729 (T)	---	729 (T)	729 (T)
STATISTICAL TESTS								
LIFE TABLE	P=0.166N	P=0.667N	P=0.648	P=0.255N	P=0.536	P=0.506N	P=0.726N	P=0.742
POLY 3	P=0.161N	P=0.693N	P=0.667	P=0.241N	P=0.563	P=0.503N	P=0.758N	P=0.760N
POLY 1.5	P=0.158N	P=0.692N	P=0.680	P=0.238N	P=0.561	P=0.503N	P=0.759	P=0.759
POLY 6	P=0.165N	P=0.694N	P=0.654	P=0.245N	P=0.564	P=0.502N	P=0.751N	P=0.759N
LOGISTIC REGRESSION	P=0.151N	P=0.674N	P=0.642N	P=0.182N	P=0.536	(e)	P=0.726N	P=0.742
COCH-ARM / FISHERS	P=0.154N	P=0.684N	P=0.684N	P=0.242N	P=0.560	P=0.500N	P=0.747	P=0.753N

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Stomach, Forestomach Squamous Cell Papilloma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	1/47.21	2/46.90	0/43.35	1/46.04	2/44.21	0/43.59	3/44.71	4/44.36
POLY-3 PERCENT (g)	2.1%	4.3%	0.0%	2.2%	4.5%	0.0%	6.7%	9.0%
TERMINAL (d)	1/37 (3%)	2/43 (5%)	0/34 (0%)	1/40 (3%)	2/35 (6%)	0/34 (0%)	3/41 (7%)	3/32 (9%)
FIRST INCIDENCE	726 (T)	726 (T)	---	726 (T)	729 (T)	---	729 (T)	712
STATISTICAL TESTS								
LIFE TABLE	P=0.558N	P=0.552	P=0.517N	P=0.744N	P=0.086	P=0.245N	P=0.572	P=0.304
POLY 3	P=0.567N	P=0.498	P=0.517N	P=0.755	P=0.113	P=0.240N	P=0.505	P=0.338
POLY 1.5	P=0.566N	P=0.497	P=0.511N	P=0.757	P=0.111	P=0.241N	P=0.498	P=0.335
POLY 6	P=0.568N	P=0.501	P=0.523N	P=0.754	P=0.114	P=0.239N	P=0.520	P=0.343
LOGISTIC REGRESSION	P=0.558N	P=0.552	(e)	P=0.744N	P=0.108	(e)	P=0.572	P=0.341
COCH-ARM / FISHERS	P=0.566N	P=0.500	P=0.500N	P=0.753N	P=0.111	P=0.247N	P=0.500	P=0.339

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Thyroid Gland: Follicular Cell Adenoma								
TUMOR RATES								
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/47.21	0/46.90	1/42.55	0/46.04	0/44.21	0/43.59	1/44.86	3/44.64
POLY-3 PERCENT (g)	2.1%	0.0%	2.4%	0.0%	0.0%	0.0%	2.2%	6.7%
TERMINAL (d)	1/37 (3%)	0/43 (0%)	1/34 (3%)	0/40 (0%)	0/35 (0%)	0/34 (0%)	0/41 (0%)	1/32 (3%)
FIRST INCIDENCE	726 (T)	---	726 (T)	---	---	---	692	653
STATISTICAL TESTS								
LIFE TABLE	P=0.459N	P=0.470N	P=0.743	P=0.484N	P=0.022 *	(e)	P=0.525	P=0.122
POLY 3	P=0.467N	P=0.501N	P=0.737	P=0.505N	P=0.023 *	(e)	P=0.503	P=0.120
POLY 1.5	P=0.465N	P=0.502N	P=0.744	P=0.503N	P=0.022 *	(e)	P=0.499	P=0.119
POLY 6	P=0.470N	P=0.499N	P=0.731	P=0.506N	P=0.023 *	(e)	P=0.510	P=0.123
LOGISTIC REGRESSION	P=0.459N	(e)	P=0.743	(e)	P=0.023 *	(e)	P=0.500	P=0.120
COCH-ARM / FISHERS	P=0.464N	P=0.500N	P=0.747	P=0.500N	P=0.022 *	(e)	P=0.500	P=0.121

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Thyroid Gland: Follicular Cell Carcinoma or Adenoma								
TUMOR RATES								
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/49 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/47.21	0/46.90	1/42.55	0/46.04	1/44.21	0/43.59	1/44.86	3/44.64
POLY-3 PERCENT (g)	2.1%	0.0%	2.4%	0.0%	2.3%	0.0%	2.2%	6.7%
TERMINAL (d)	1/37 (3%)	0/43 (0%)	1/34 (3%)	0/40 (0%)	1/35 (3%)	0/34 (0%)	0/41 (0%)	1/32 (3%)
FIRST INCIDENCE	726 (T)	---	726 (T)	---	729 (T)	---	692	653
STATISTICAL TESTS								
LIFE TABLE	P=0.459N	P=0.470N	P=0.743	P=0.484N	P=0.078	P=0.506N	P=0.728N	P=0.296
POLY 3	P=0.467N	P=0.501N	P=0.737	P=0.505N	P=0.084	P=0.503N	P=0.757N	P=0.309
POLY 1.5	P=0.465N	P=0.502N	P=0.744	P=0.503N	P=0.083	P=0.503N	P=0.760	P=0.305
POLY 6	P=0.470N	P=0.499N	P=0.731	P=0.506N	P=0.085	P=0.502N	P=0.750N	P=0.314
LOGISTIC REGRESSION	P=0.459N	(e)	P=0.743	(e)	P=0.082	(e)	P=0.761N	P=0.304
COCH-ARM / FISHERS	P=0.464N	P=0.500N	P=0.747	P=0.500N	P=0.082	P=0.500N	P=0.753N	P=0.309

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Uterus Leiomyosarcoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)					0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)					0/44.21	1/43.59	0/44.71	2/44.76
POLY-3 PERCENT (g)					0.0%	2.3%	0.0%	4.5%
TERMINAL (d)					0/35 (0%)	1/34 (3%)	0/41 (0%)	0/32 (0%)
FIRST INCIDENCE					---	729 (T)	---	595
STATISTICAL TESTS								
LIFE TABLE					P=0.140	P=0.494	(e)	P=0.234
POLY 3					P=0.150	P=0.497	(e)	P=0.240
POLY 1.5					P=0.149	P=0.497	(e)	P=0.237
POLY 6					P=0.152	P=0.498	(e)	P=0.243
LOGISTIC REGRESSION					P=0.149	P=0.494	(e)	P=0.243
COCH-ARM / FISHERS					P=0.149	P=0.500	(e)	P=0.247

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
Uterus Polyp Stromal								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)					1/50 (2%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)					1/44.21	0/43.59	3/44.71	1/44.68
POLY-3 PERCENT (g)					2.3%	0.0%	6.7%	2.2%
TERMINAL (d)					1/35 (3%)	0/34 (0%)	3/41 (7%)	0/32 (0%)
FIRST INCIDENCE					729 (T)	---	729 (T)	619
STATISTICAL TESTS								
LIFE TABLE					P=0.567	P=0.506N	P=0.363	P=0.748
POLY 3					P=0.602	P=0.503N	P=0.309	P=0.758N
POLY 1.5					P=0.596	P=0.503N	P=0.303	P=0.760
POLY 6					P=0.609	P=0.502N	P=0.321	P=0.755N
LOGISTIC REGRESSION					P=0.593	(e)	P=0.363	P=0.760N
COCH-ARM / FISHERS					P=0.592	P=0.500N	P=0.309	P=0.753N

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	Males 200 MG/KG	Males 630 MG/KG	Males 2000 MG/KG	Females 0 MG/KG	Females 100 MG/KG	Females 300 MG/KG	Females 1000 MG/KG
All Organs Hemangioma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.21	1/46.90	0/43.35	2/46.04	1/44.21	0/43.59	0/44.71	0/44.29
POLY-3 PERCENT (g)	2.1%	2.1%	0.0%	4.3%	2.3%	0.0%	0.0%	0.0%
TERMINAL (d)	1/37 (3%)	1/43 (2%)	0/34 (0%)	2/40 (5%)	1/35 (3%)	0/34 (0%)	0/41 (0%)	0/32 (0%)
FIRST INCIDENCE	726 (T)	726 (T)	---	726 (T)	729 (T)	---	---	---
STATISTICAL TESTS								
LIFE TABLE	P=0.338	P=0.728N	P=0.517N	P=0.527	P=0.515N	P=0.506N	P=0.468N	P=0.518N
POLY 3	P=0.325	P=0.759	P=0.517N	P=0.491	P=0.499N	P=0.503N	P=0.498N	P=0.500N
POLY 1.5	P=0.327	P=0.759	P=0.511N	P=0.494	P=0.498N	P=0.503N	P=0.501N	P=0.501N
POLY 6	P=0.323	P=0.760N	P=0.523N	P=0.489	P=0.501N	P=0.502N	P=0.491N	P=0.498N
LOGISTIC REGRESSION	P=0.338	P=0.728N	(e)	P=0.527	P=0.515N	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.329	P=0.753N	P=0.500N	P=0.500	P=0.500N	P=0.500N	P=0.500N	P=0.500N

Dose	Males 0 MG/KG	Males 200 MG/KG	Males 630 MG/KG	Males 2000 MG/KG	Females 0 MG/KG	Females 100 MG/KG	Females 300 MG/KG	Females 1000 MG/KG
All Organs Hemangiosarcoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	9/50 (18%)	2/50 (4%)	3/50 (6%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	3/47.72	2/46.90	9/44.70	2/46.42	3/44.60	1/43.59	1/44.71	2/44.34
POLY-3 PERCENT (g)	6.3%	4.3%	20.1%	4.3%	6.7%	2.3%	2.2%	4.5%
TERMINAL (d)	1/37 (3%)	2/43 (5%)	5/34 (15%)	1/40 (3%)	2/35 (6%)	1/34 (3%)	1/41 (2%)	1/32 (3%)
FIRST INCIDENCE	624	726 (T)	517	618	619	729 (T)	729 (T)	717
STATISTICAL TESTS								
LIFE TABLE	P=0.430N	P=0.461N	P=0.048 *	P=0.502N	P=0.628	P=0.316N	P=0.268N	P=0.529N
POLY 3	P=0.442N	P=0.508N	P=0.046 *	P=0.513N	P=0.613N	P=0.313N	P=0.304N	P=0.503N
POLY 1.5	P=0.434N	P=0.506N	P=0.051	P=0.508N	P=0.614N	P=0.313N	P=0.309N	P=0.504N
POLY 6	P=0.451N	P=0.507N	P=0.042 *	P=0.517N	P=0.613N	P=0.313N	P=0.295N	P=0.501N
LOGISTIC REGRESSION	P=0.415N	P=0.491N	P=0.080	P=0.449N	P=0.614N	P=0.309N	P=0.306N	P=0.501N
COCH-ARM / FISHERS	P=0.425N	P=0.500N	P=0.061	P=0.500N	P=0.616N	P=0.309N	P=0.309N	P=0.500N

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
All Organs Hemangiosarcoma or Hemangioma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	4/50 (8%)	3/50 (6%)	9/50 (18%)	4/50 (8%)	4/50 (8%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	4/47.72	3/46.90	9/44.70	4/46.42	4/44.60	1/43.59	1/44.71	2/44.34
POLY-3 PERCENT (g)	8.4%	6.4%	20.1%	8.6%	9.0%	2.3%	2.2%	4.5%
TERMINAL (d)	2/37 (5%)	3/43 (7%)	5/34 (15%)	3/40 (8%)	3/35 (9%)	1/34 (3%)	1/41 (2%)	1/32 (3%)
FIRST INCIDENCE	624	726 (T)	517	618	619	729 (T)	729 (T)	717
STATISTICAL TESTS								
LIFE TABLE	P=0.566	P=0.444N	P=0.092	P=0.626N	P=0.515N	P=0.190N	P=0.147N	P=0.371N
POLY 3	P=0.550	P=0.509N	P=0.092	P=0.628	P=0.477N	P=0.185N	P=0.178N	P=0.340N
POLY 1.5	P=0.557	P=0.508N	P=0.100	P=0.633	P=0.478N	P=0.185N	P=0.182N	P=0.342N
POLY 6	P=0.540	P=0.508N	P=0.085	P=0.623	P=0.478N	P=0.185N	P=0.169N	P=0.338N
LOGISTIC REGRESSION	P=0.573	P=0.499N	P=0.141	P=0.625N	P=0.478N	P=0.183N	P=0.178N	P=0.336N
COCH-ARM / FISHERS	P=0.568	P=0.500N	P=0.117	P=0.643N	P=0.482N	P=0.181N	P=0.181N	P=0.339N

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
All Organs Histiocytic Sarcoma								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	4/50 (8%)	5/50 (10%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/47.21	1/46.96	0/43.35	2/46.20	4/45.59	5/45.24	0/44.71	3/45.07
POLY-3 PERCENT (g)	0.0%	2.1%	0.0%	4.3%	8.8%	11.1%	0.0%	6.7%
TERMINAL (d)	0/37 (0%)	0/43 (0%)	0/34 (0%)	1/40 (3%)	0/35 (0%)	2/34 (6%)	0/41 (0%)	1/32 (3%)
FIRST INCIDENCE	---	710	---	684	617	444	---	617
STATISTICAL TESTS								
LIFE TABLE	P=0.150	P=0.514	(e)	P=0.241	P=0.409N	P=0.498	P=0.067N	P=0.515N
POLY 3	P=0.147	P=0.499	(e)	P=0.232	P=0.396N	P=0.495	P=0.063N	P=0.506N
POLY 1.5	P=0.148	P=0.498	(e)	P=0.234	P=0.396N	P=0.494	P=0.063N	P=0.507N
POLY 6	P=0.146	P=0.501	(e)	P=0.232	P=0.398N	P=0.494	P=0.061N	P=0.507N
LOGISTIC REGRESSION	P=0.149	P=0.499	(e)	P=0.237	P=0.381N	P=0.565	P=0.050N	P=0.470N
COCH-ARM / FISHERS	P=0.150	P=0.500	(e)	P=0.247	P=0.395N	P=0.500	P=0.059N	P=0.500N

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
All Organs Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	8/50 (16%)	9/50 (18%)	6/50 (12%)	8/50 (16%)
POLY-3 RATE (b)	0/47.21	0/46.90	1/43.35	1/46.04	8/44.21	9/44.42	6/45.55	8/44.90
POLY-3 PERCENT (g)	0.0%	0.0%	2.3%	2.2%	18.1%	20.3%	13.2%	17.8%
TERMINAL (d)	0/37 (0%)	0/43 (0%)	1/34 (3%)	1/40 (3%)	8/35 (23%)	6/34 (18%)	3/41 (7%)	6/32 (19%)
FIRST INCIDENCE	---	---	726 (T)	726 (T)	729 (T)	610	586	567
STATISTICAL TESTS								
LIFE TABLE	P=0.322	(e)	P=0.483	P=0.516	P=0.541	P=0.483	P=0.288N	P=0.541
POLY 3	P=0.307	(e)	P=0.483	P=0.495	P=0.530N	P=0.504	P=0.363N	P=0.595N
POLY 1.5	P=0.311	(e)	P=0.489	P=0.497	P=0.536N	P=0.494	P=0.383N	P=0.606N
POLY 6	P=0.303	(e)	P=0.477	P=0.494	P=0.527N	P=0.523	P=0.329N	P=0.581N
LOGISTIC REGRESSION	(e)	(e)	P=0.483	P=0.516	P=0.536N	P=0.491	P=0.378N	P=0.600N
COCH-ARM / FISHERS	P=0.315	(e)	P=0.500	P=0.500	P=0.540N	P=0.500	P=0.387N	P=0.607N

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
All Organs Benign Tumors								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	30/50 (60%)	25/50 (50%)	32/50 (64%)	32/50 (64%)	24/50 (48%)	28/50 (56%)	27/50 (54%)	38/50 (76%)
POLY-3 RATE (b)	30/48.13	25/46.90	32/45.49	32/48.33	24/45.52	28/44.74	27/46.13	38/47.60
POLY-3 PERCENT (g)	62.3%	53.3%	70.4%	66.2%	52.7%	62.6%	58.5%	79.8%
TERMINAL (d)	27/37 (73%)	25/43 (58%)	23/34 (68%)	27/40 (68%)	20/35 (57%)	23/34 (68%)	24/41 (59%)	27/32 (84%)
FIRST INCIDENCE	511	726 (T)	487	399	617	594	444	70
STATISTICAL TESTS								
LIFE TABLE	P=0.254	P=0.043N*	P=0.231	P=0.578	P<0.001 **	P=0.241	P=0.536N	P=0.003 **
POLY 3	P=0.241	P=0.245N	P=0.269	P=0.426	P=0.003 **	P=0.226	P=0.362	P=0.003 **
POLY 1.5	P=0.232	P=0.237N	P=0.317	P=0.421	P=0.003 **	P=0.232	P=0.335	P=0.003 **
POLY 6	P=0.252	P=0.240N	P=0.247	P=0.440	P=0.004 **	P=0.225	P=0.410	P=0.004 **
LOGISTIC REGRESSION	P=0.179	P=0.199N	P=0.209	P=0.390	P=0.002 **	P=0.248	P=0.348	P=0.003 **
COCH-ARM / FISHERS	P=0.215	P=0.211N	P=0.418	P=0.418	P=0.003 **	P=0.274	P=0.345	P=0.004 **

Statistical Analysis of Primary Tumors in Mice(B6C3F1) - TRIETHANOLAMINE

Terminal Sacrifice at 104 weeks

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
All Organs Malignant Tumors								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	28/50 (56%)	24/50 (48%)	27/50 (54%)	21/50 (42%)	27/50 (54%)	26/50 (52%)	16/50 (32%)	21/50 (42%)
POLY-3 RATE (b)	28/50.00	24/48.24	27/48.83	21/48.31	27/48.01	26/47.70	16/46.06	21/46.59
POLY-3 PERCENT (g)	56.0%	49.8%	55.3%	43.5%	56.2%	54.5%	34.7%	45.1%
TERMINAL (d)	16/37 (43%)	20/43 (47%)	14/34 (41%)	14/40 (35%)	16/35 (46%)	14/34 (41%)	12/41 (29%)	12/32 (38%)
FIRST INCIDENCE	511	554	439	566	532	444	573	567
STATISTICAL TESTS								
LIFE TABLE	P=0.174N	P=0.169N	P=0.454	P=0.135N	P=0.261N	P=0.521N	P=0.015N*	P=0.270N
POLY 3	P=0.150N	P=0.339N	P=0.552N	P=0.149N	P=0.179N	P=0.514N	P=0.027N*	P=0.188N
POLY 1.5	P=0.141N	P=0.318N	P=0.532N	P=0.136N	P=0.170N	P=0.521N	P=0.026N*	P=0.181N
POLY 6	P=0.160N	P=0.357N	P=0.574N	P=0.163N	P=0.196N	P=0.505N	P=0.028N*	P=0.203N
LOGISTIC REGRESSION	P=0.112N	P=0.263N	P=0.291N	P=0.088N	P=0.159N	P=0.495N	P=0.022N*	P=0.160N
COCH-ARM / FISHERS	P=0.128N	P=0.274N	P=0.500N	P=0.115N	P=0.158N	P=0.500N	P=0.021N*	P=0.158N

Dose	Males 0 MG/KG	200 MG/KG	630 MG/KG	2000 MG/KG	Females 0 MG/KG	100 MG/KG	300 MG/KG	1000 MG/KG
All Organs Malignant and Benign Tumors								
TUMOR RATES	#	#	#	#	#	#	#	#
OVERALL (a)	45/50 (90%)	35/50 (70%)	43/50 (86%)	41/50 (82%)	38/50 (76%)	41/50 (82%)	35/50 (70%)	44/50 (88%)
POLY-3 RATE (b)	45/50.00	35/48.24	43/49.23	41/49.70	38/48.01	41/48.06	35/47.33	44/49.06
POLY-3 PERCENT (g)	90.0%	72.6%	87.4%	82.5%	79.2%	85.3%	74.0%	89.7%
TERMINAL (d)	33/37 (89%)	31/43 (72%)	28/34 (82%)	32/40 (80%)	27/35 (77%)	27/34 (79%)	29/41 (71%)	29/32 (91%)
FIRST INCIDENCE	511	554	439	399	532	444	444	70
STATISTICAL TESTS								
LIFE TABLE	P=0.516N	P=0.005N**	P=0.421	P=0.180N	P=0.084	P=0.332	P=0.123N	P=0.104
POLY 3	P=0.518N	P=0.022N*	P=0.460N	P=0.212N	P=0.122	P=0.300	P=0.359N	P=0.119
POLY 1.5	P=0.530N	P=0.017N*	P=0.433N	P=0.204N	P=0.115	P=0.278	P=0.370N	P=0.109
POLY 6	P=0.518N	P=0.027N*	P=0.479N	P=0.225N	P=0.125	P=0.337	P=0.339N	P=0.129
LOGISTIC REGRESSION	P=0.556	P=0.014N*	P=0.353N	P=0.175N	P=0.088	P=0.260	P=0.352N	P=0.088
COCH-ARM / FISHERS	P=0.559	P=0.011N*	P=0.380N	P=0.194N	P=0.095	P=0.312	P=0.326N	P=0.096

(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).