FYI-0703-01457
MR 269758

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
P. O. Box 12233
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September 12, 2003

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Dear Document Control Office (7407):

In compliance with the National Toxicology Program's (NTP) mission to keep our colleagues informed of the current NTP findings during ongoing studies, a copy of the **revised** Summary Pathology Tables for five chronic studies from our Toxic Equivalency Factor Evaluations. The studies are PECDF, PCB 126, PCB 153, TCDD and Dioxin Mixture (PECDF, PCB 126 and TCDD). The Neo-Plastic and Non-Neoplastic reports were re-generated as a result of an extended pathology evaluation of the liver.

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. 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.

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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

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

Encl: Revised Pathology Tables
cc: Central Data Management

National Toxicology Program

TR-525 Toxic Equivalency Factor Evaluation (PeCDF)

Revised Pathology Tables – Female Rats Core Study

- **P03 - Incidence Rates of Non-Neoplastic Lesions**
- **P05 - Incidence Rates of Neoplasms by Anatomic Site (systemic lesions abridged)**
- **P08 - Statistical Analysis of Primary Tumors (control vs stop group)**
- **P08 - Statistical Analysis of Primary Tumors (control vs treated group)**
- **P18 - Incidence Rates of Non-Neoplastic Lesions**

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
TOXIC EQUIVALENCY FACTOR EVALUATION(PECDF)

FINAL #2 RATS

Facility: Battelle Columbus Laboratory

Chemical CAS #: 57117-31-4

Lock Date: 07/25/02

Cage Range: All

Reasons For Removal:	25018 Dosing Accident	25019 Moribund Sacrifice
	25020 Natural Death	25021 Terminal Sacrifice
Removal Date Range:	All	
Treatment Groups:	Include All	

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
DISPOSITION SUMMARY						
Animals Initially In Study	98	98	98	98	98	98
Early Deaths						
Natural Death	7	10	10	8	14	11
Moribund Sacrifice	21	20	17	19	19	19
Dosing Accident		1	2	1		
Survivors						
Terminal Sacrifice	25	22	24	25	20	23
Animals Examined Microscopically	53	53	53	53	53	53
ALIMENTARY SYSTEM						
Esophagus	(53)	(53)	(52)	(53)	(53)	(53)
Cyst				2 (4%)		
Perforation		1 (2%)	2 (4%)	1 (2%)		
Muscularis, Inflammation		2 (4%)	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Periesophageal Tissue, Inflammation		1 (2%)	2 (4%)	2 (4%)	1 (2%)	
Intestine Large, Colon	(53)	(53)	(53)	(53)	(51)	(53)
Edema					1 (2%)	
Inflammation					1 (2%)	1 (2%)
Parasite Metazoan	2 (4%)					
Intestine Large, Rectum	(53)	(53)	(53)	(53)	(52)	(53)
Parasite Metazoan	4 (8%)	5 (9%)	5 (9%)	1 (2%)	1 (2%)	1 (2%)
Artery, Inflammation, Chronic Active		1 (2%)		1 (2%)		
Intestine Large, Cecum	(53)	(53)	(53)	(52)	(51)	(53)
Inflammation					1 (2%)	
Artery, Inflammation, Chronic Active		1 (2%)				2 (4%)
Artery, Mineralization					1 (2%)	
Intestine Small, Ileum	(53)	(53)	(53)	(52)	(52)	(53)
Parasite Metazoan	1 (2%)					
Liver	(53)	(53)	(53)	(52)	(53)	(53)
Angiectasis	6 (11%)	3 (6%)	4 (8%)	1 (2%)		1 (2%)
Basophilic Focus	10 (19%)	11 (21%)	9 (17%)	10 (19%)	12 (23%)	6 (11%)
Basophilic Focus, Multiple	12 (23%)	12 (23%)	11 (21%)	6 (12%)	3 (6%)	1 (2%)
Cholangiofibrosis		1 (2%)		3 (6%)	3 (6%)	5 (9%)
Clear Cell Focus	11 (21%)	1 (2%)	7 (13%)	2 (4%)		3 (6%)
Clear Cell Focus, Multiple	2 (4%)	5 (9%)	3 (6%)	1 (2%)	6 (11%)	8 (15%)
Degeneration, Cystic						1 (2%)
Eosinophilic Focus	7 (13%)	11 (21%)	9 (17%)	9 (17%)	11 (21%)	10 (19%)
Eosinophilic Focus, Multiple	8 (15%)	2 (4%)	9 (17%)	9 (17%)	12 (23%)	18 (34%)
Fatty Change, Diffuse	1 (2%)	4 (8%)	10 (19%)	12 (23%)	20 (38%)	26 (49%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
ALIMENTARY SYSTEM - CONT						
Fatty Change, Focal	5 (9%)	6 (11%)	5 (9%)	6 (12%)	6 (11%)	4 (8%)
Hematopoietic Cell Proliferation	24 (45%)	28 (53%)	27 (51%)	24 (46%)	39 (74%)	31 (58%)
Hemorrhage	1 (2%)					
Hepatodiaphragmatic Nodule	3 (6%)	3 (6%)	3 (6%)	1 (2%)	1 (2%)	1 (2%)
Hyperplasia, Nodular				3 (6%)	8 (15%)	12 (23%)
Inflammation	47 (89%)	44 (83%)	47 (89%)	50 (96%)	48 (91%)	50 (94%)
Mixed Cell Focus	5 (9%)		1 (2%)	2 (4%)	2 (4%)	1 (2%)
Mixed Cell Focus, Multiple	28 (53%)	24 (45%)	23 (43%)	27 (52%)	25 (47%)	25 (47%)
Necrosis	4 (8%)	10 (19%)	3 (6%)	3 (6%)	6 (11%)	18 (34%)
Pigmentation	13 (25%)	11 (21%)	21 (40%)	44 (85%)	42 (79%)	48 (91%)
Toxic Hepatopathy		2 (4%)	3 (6%)	8 (15%)	27 (51%)	44 (83%)
Artery, Inflammation, Chronic Active						1 (2%)
Bile Duct, Cyst	7 (13%)	4 (8%)	2 (4%)	3 (6%)	2 (4%)	7 (13%)
Bile Duct, Fibrosis	1 (2%)	4 (8%)	2 (4%)	2 (4%)	3 (6%)	6 (11%)
Bile Duct, Hyperplasia	3 (6%)	2 (4%)	2 (4%)	2 (4%)	1 (2%)	13 (25%)
Centrilobular, Degeneration	4 (8%)	2 (4%)	3 (6%)	4 (8%)	4 (8%)	5 (9%)
Hepatocyte, Hypertrophy	2 (4%)	13 (25%)	17 (32%)	17 (33%)	24 (45%)	34 (64%)
Hepatocyte, Multinucleated			4 (8%)	13 (25%)	18 (34%)	35 (66%)
Oval Cell, Hyperplasia	1 (2%)	4 (8%)	2 (4%)	6 (12%)	15 (28%)	35 (66%)
Portal, Fibrosis						1 (2%)
Mesentery	(1)	(2)	(1)	(3)	(2)	(4)
Inflammation		1 (50%)				
Necrosis			1 (100%)			
Artery, Inflammation, Chronic Active		1 (50%)		2 (67%)	1 (50%)	4 (100%)
Fat, Necrosis	1 (100%)			1 (33%)	1 (50%)	
Oral Mucosa	(52)	(53)	(52)	(53)	(53)	(53)
Gingival, Cyst				1 (2%)		
Gingival, Hyperplasia				1 (2%)		
Gingival, Hyperplasia, Squamous	15 (29%)	11 (21%)	16 (31%)	19 (36%)	22 (42%)	20 (38%)
Pancreas	(53)	(53)	(53)	(52)	(52)	(52)
Cyst					1 (2%)	
Cytoplasmic Alteration						3 (6%)
Inflammation, Chronic Active	2 (4%)	1 (2%)	1 (2%)	1 (2%)		4 (8%)
Lipomatosis				1 (2%)		
Acinus, Atrophy	3 (6%)	1 (2%)	1 (2%)	1 (2%)		3 (6%)
Acinus, Hyperplasia		1 (2%)				
Acinus, Vacuolization Cytoplasmic					2 (4%)	23 (44%)
Artery, Inflammation, Chronic Active	1 (2%)	2 (4%)	1 (2%)	2 (4%)	4 (8%)	11 (21%)
Duct, Dilatation						1 (2%)
Salivary Glands	(53)	(53)	(51)	(53)	(51)	(51)
Atrophy	1 (2%)					2 (4%)
Duct, Inflammation		1 (2%)				
Stomach, Forestomach	(53)	(53)	(53)	(53)	(52)	(53)

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
ALIMENTARY SYSTEM - CONT						
Cyst						1 (2%)
Edema		1 (2%)				
Hyperkeratosis			1 (2%)			
Hyperplasia, Squamous	4 (8%)	1 (2%)	5 (9%)	6 (11%)	3 (6%)	10 (19%)
Inflammation	1 (2%)	1 (2%)		2 (4%)	2 (4%)	2 (4%)
Mineralization				1 (2%)		
Ulcer		1 (2%)	2 (4%)	2 (4%)	1 (2%)	1 (2%)
Artery, Inflammation, Chronic Active					1 (2%)	3 (6%)
Stomach, Glandular	(53)	(53)	(53)	(53)	(52)	(53)
Erosion			1 (2%)	2 (4%)	1 (2%)	
Hyperplasia				1 (2%)		
Inflammation	1 (2%)			1 (2%)		
Mineralization	2 (4%)	9 (17%)	1 (2%)	3 (6%)	2 (4%)	4 (8%)
Ulcer	1 (2%)					
Artery, Inflammation, Chronic Active					1 (2%)	1 (2%)
Serosa, Inflammation		1 (2%)				
Tooth	(33)	(25)	(22)	(30)	(29)	(29)
Peridontal Tissue, Inflammation	33 (100%)	25 (100%)	22 (100%)	30 (100%)	29 (100%)	29 (100%)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(53)	(53)	(53)	(53)	(53)	(53)
Aorta, Mineralization		1 (2%)		1 (2%)	2 (4%)	
Aorta, Adventitia, Inflammation, Chronic Active					1 (2%)	
Heart	(53)	(53)	(52)	(53)	(53)	(52)
Cardiomyopathy	15 (28%)	12 (23%)	19 (37%)	13 (25%)	18 (34%)	24 (46%)
Hemorrhage	2 (4%)					
Infiltration Cellular, Mononuclear Cell						1 (2%)
Inflammation	1 (2%)		1 (2%)	1 (2%)		
Mineralization				1 (2%)	1 (2%)	1 (2%)
Artery, Inflammation, Chronic Active					1 (2%)	2 (4%)
Epicardium, Inflammation		1 (2%)				1 (2%)
ENDOCRINE SYSTEM						
Adrenal Cortex	(53)	(53)	(53)	(52)	(53)	(53)
Angiectasis	31 (58%)	37 (70%)	30 (57%)	33 (63%)	27 (51%)	35 (66%)
Atrophy	3 (6%)			1 (2%)		4 (8%)
Degeneration, Cystic	4 (8%)	17 (32%)	14 (26%)	18 (35%)	12 (23%)	14 (26%)
Hematopoietic Cell Proliferation			1 (2%)		1 (2%)	1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
ENDOCRINE SYSTEM - CONT						
Hemorrhage	1 (2%)			1 (2%)		
Hyperplasia	8 (15%)	10 (19%)	10 (19%)	7 (13%)	10 (19%)	11 (21%)
Hypertrophy	42 (79%)	43 (81%)	43 (81%)	46 (88%)	44 (83%)	45 (85%)
Necrosis	4 (8%)		2 (4%)		2 (4%)	
Vacuolization Cytoplasmic	9 (17%)	13 (25%)	14 (26%)	7 (13%)	17 (32%)	9 (17%)
Adrenal Medulla	(53)	(53)	(53)	(52)	(53)	(53)
Hyperplasia	11 (21%)	12 (23%)	14 (26%)	14 (27%)	7 (13%)	10 (19%)
Islets, Pancreatic	(53)	(53)	(53)	(52)	(52)	(52)
Hyperplasia						2 (4%)
Parathyroid Gland	(49)	(51)	(44)	(51)	(49)	(49)
Hyperplasia		1 (2%)	1 (2%)		1 (2%)	1 (2%)
Hypertrophy		1 (2%)				
Pituitary Gland	(53)	(53)	(53)	(53)	(53)	(53)
Angiectasis	20 (38%)	21 (40%)	20 (38%)	13 (25%)	12 (23%)	14 (26%)
Atrophy	1 (2%)					
Cyst	2 (4%)			1 (2%)	1 (2%)	1 (2%)
Cytoplasmic Alteration	1 (2%)				1 (2%)	
Vacuolization Cytoplasmic	2 (4%)	2 (4%)	1 (2%)			
Pars Distalis, Hyperplasia	22 (42%)	16 (30%)	14 (26%)	11 (21%)	15 (28%)	19 (36%)
Pars Intermedia, Hyperplasia	1 (2%)					
Rathke's Cleft, Pars Intermedia, Hyperplasia					1 (2%)	
Thyroid Gland	(53)	(53)	(51)	(53)	(51)	(51)
Inflammation			1 (2%)			
C-Cell, Hyperplasia	15 (28%)	16 (30%)	9 (18%)	13 (25%)	9 (18%)	11 (22%)
Follicle, Cyst	1 (2%)			1 (2%)	1 (2%)	
Follicular Cell, Hypertrophy	7 (13%)	13 (25%)	24 (47%)	24 (45%)	24 (47%)	22 (43%)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(53)	(51)	(53)	(53)	(50)	(53)
Hyperplasia, Squamous			1 (2%)			
Inflammation	52 (98%)	47 (92%)	46 (87%)	51 (96%)	47 (94%)	47 (89%)
Duct, Cyst	40 (75%)	37 (73%)	34 (64%)	41 (77%)	44 (88%)	40 (75%)
Ovary	(53)	(53)	(53)	(52)	(52)	(53)
Atrophy	43 (81%)	40 (75%)	38 (72%)	43 (83%)	45 (87%)	45 (85%)
Cyst	11 (21%)	18 (34%)	20 (38%)	17 (33%)	18 (35%)	13 (25%)
Fibrosis				1 (2%)		

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
GENITAL SYSTEM - CONT						
Inflammation, Chronic Active	1 (2%)				1 (2%)	1 (2%)
Oviduct	(1)				(1)	
Cyst	1 (100%)					
Inflammation, Chronic Active					1 (100%)	
Uterus	(53)	(53)	(53)	(52)	(52)	(53)
Adenomyosis	1 (2%)			1 (2%)	1 (2%)	
Cyst		1 (2%)			1 (2%)	
Hemorrhage					1 (2%)	2 (4%)
Inflammation, Chronic Active		5 (9%)	3 (6%)	3 (6%)	4 (8%)	3 (6%)
Inflammation, Suppurative	3 (6%)	6 (11%)	1 (2%)	7 (13%)	3 (6%)	4 (8%)
Metaplasia, Squamous	17 (32%)	25 (47%)	21 (40%)	36 (69%)	31 (60%)	35 (66%)
Ulcer				1 (2%)	3 (6%)	1 (2%)
Cervix, Cyst						1 (2%)
Endometrium, Hyperplasia, Cystic	31 (58%)	29 (55%)	29 (55%)	33 (63%)	39 (75%)	37 (70%)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(53)	(53)	(53)	(53)	(53)
Atrophy			2 (4%)			
Hyperplasia	38 (72%)	32 (60%)	37 (70%)	35 (66%)	42 (79%)	41 (77%)
Hyperplasia, Reticulum Cell				1 (2%)		
Lymph Node	(5)	(4)	(4)	(4)	(3)	(7)
Hyperplasia, Plasma Cell						1 (14%)
Iliac, Ectasia		1 (25%)				
Lumbar, Ectasia	2 (40%)	1 (25%)			1 (33%)	
Lumbar, Hemorrhage	2 (40%)	1 (25%)				
Lumbar, Hyperplasia, Histiocytic				1 (25%)	1 (33%)	
Lumbar, Hyperplasia, Plasma Cell		1 (25%)	1 (25%)	1 (25%)		1 (14%)
Mediastinal, Ectasia					2 (67%)	2 (29%)
Mediastinal, Hemorrhage			1 (25%)			1 (14%)
Mediastinal, Hyperplasia, Lymphoid			1 (25%)			
Mediastinal, Hyperplasia, Plasma Cell		1 (25%)		1 (25%)	1 (33%)	2 (29%)
Popliteal, Ectasia	1 (20%)					
Lymph Node, Mandibular	(53)	(53)	(51)	(53)	(51)	(51)
Congestion			1 (2%)			
Ectasia		1 (2%)	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Hyperplasia, Histiocytic		1 (2%)				
Hyperplasia, Lymphoid				1 (2%)		1 (2%)
Hyperplasia, Plasma Cell	38 (72%)	40 (75%)	38 (75%)	31 (58%)	30 (59%)	29 (57%)
Lymph Node, Mesenteric	(53)	(53)	(53)	(52)	(52)	(53)
Atrophy				1 (2%)		
Hemorrhage	1 (2%)		1 (2%)			1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
HEMATOPOIETIC SYSTEM - CONT						
Hyperplasia, Histiocytic						1 (2%)
Hyperplasia, Lymphoid		1 (2%)	1 (2%)			1 (2%)
Hyperplasia, Plasma Cell		1 (2%)				1 (2%)
Spleen	(53)	(53)	(53)	(52)	(52)	(51)
Accessory Spleen	1 (2%)		1 (2%)			
Congestion		1 (2%)			1 (2%)	
Hematopoietic Cell Proliferation	49 (92%)	49 (92%)	48 (91%)	51 (98%)	46 (88%)	50 (98%)
Hemorrhage		1 (2%)				
Infarct			1 (2%)			
Necrosis		1 (2%)				
Pigmentation	52 (98%)	45 (85%)	50 (94%)	48 (92%)	49 (94%)	51 (100%)
Lymphatic, Angiectasis			1 (2%)			
Lymphoid Follicle, Atrophy	7 (13%)	8 (15%)	7 (13%)	6 (12%)	12 (23%)	4 (8%)
Red Pulp, Atrophy	2 (4%)					
Red Pulp, Hyperplasia		1 (2%)				
Thymus	(53)	(49)	(50)	(52)	(49)	(51)
Atrophy	43 (81%)	36 (73%)	36 (72%)	44 (85%)	39 (80%)	48 (94%)
Hemorrhage	1 (2%)		1 (2%)		1 (2%)	1 (2%)
Hyperplasia, Lymphoid			1 (2%)			
Inflammation		1 (2%)				
INTEGUMENTARY SYSTEM						
Mammary Gland	(53)	(53)	(53)	(53)	(53)	(53)
Cyst	1 (2%)	2 (4%)		5 (9%)	4 (8%)	3 (6%)
Hyperplasia	33 (62%)	29 (55%)	26 (49%)	20 (38%)	20 (38%)	17 (32%)
Inflammation, Granulomatous	2 (4%)	4 (8%)	3 (6%)	4 (8%)	4 (8%)	3 (6%)
Skin	(53)	(53)	(53)	(53)	(53)	(53)
Inflammation	2 (4%)	1 (2%)				
Ulcer	2 (4%)	1 (2%)				
Conjunctiva, Inflammation						1 (2%)
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
Brain	(53)	(53)	(53)	(53)	(53)	(53)
Edema				1 (2%)		

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
NERVOUS SYSTEM - CONT						
Gliosis				1 (2%)		
Hemorrhage	1 (2%)					1 (2%)
Hydrocephalus	1 (2%)			1 (2%)		1 (2%)
Peripheral Nerve				(1)		(1)
Radicular Neuropathy						1 (100%)
Spinal Cord				(1)		(1)
Degeneration						1 (100%)
Hemorrhage				1 (100%)		
Necrosis				1 (100%)		
RESPIRATORY SYSTEM						
Lung	(53)	(53)	(53)	(53)	(53)	(52)
Edema					1 (2%)	
Hemorrhage					1 (2%)	
Infiltration Cellular, Histiocyte	44 (83%)	44 (83%)	40 (75%)	40 (75%)	41 (77%)	36 (69%)
Inflammation	5 (9%)	8 (15%)	7 (13%)	6 (11%)	7 (13%)	8 (15%)
Metaplasia, Squamous				2 (4%)	4 (8%)	3 (6%)
Mineralization				1 (2%)	1 (2%)	
Alveolar Epithelium, Hyperplasia	14 (26%)	17 (32%)	12 (23%)	20 (38%)	8 (15%)	3 (6%)
Alveolar Epithelium, Metaplasia, Bronchiolar	5 (9%)	6 (11%)	5 (9%)	9 (17%)	23 (43%)	28 (54%)
Alveolus, Metaplasia, Squamous			1 (2%)			
Nose	(53)	(53)	(53)	(53)	(53)	(53)
Inflammation	8 (15%)	3 (6%)	8 (15%)	11 (21%)	7 (13%)	6 (11%)
Mineralization	1 (2%)					
Olfactory Epithelium, Metaplasia			1 (2%)			
Respiratory Epithelium, Hyperplasia	1 (2%)	1 (2%)	2 (4%)	1 (2%)	6 (11%)	3 (6%)
Respiratory Epithelium, Metaplasia						1 (2%)
Septum, Inflammation	1 (2%)	2 (4%)	3 (6%)	2 (4%)	5 (9%)	3 (6%)
Squamous Epithelium, Hyperplasia	1 (2%)	1 (2%)	1 (2%)			
Trachea	(53)	(53)	(52)	(53)	(53)	(53)
Inflammation					1 (2%)	1 (2%)
Artery, Peritracheal Tissue, Inflammation, Chronic Active						1 (2%)
Peritracheal Tissue, Inflammation		1 (2%)	2 (4%)	1 (2%)		
SPECIAL SENSES SYSTEM						
Eye	(53)	(53)	(52)	(53)	(52)	(52)
Hemorrhage		1 (2%)				
Inflammation		1 (2%)			1 (2%)	

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
SPECIAL SENSES SYSTEM - CONT						
Cornea, Inflammation						1 (2%)
Lens, Degeneration		1 (2%)				
Retina, Atrophy			1 (2%)			
Retina, Degeneration		1 (2%)				
Harderian Gland	(53)	(53)	(53)	(53)	(52)	(52)
Inflammation	16 (30%)	9 (17%)	10 (19%)	13 (25%)	8 (15%)	6 (12%)
URINARY SYSTEM						
Kidney	(53)	(53)	(53)	(52)	(53)	(53)
Accumulation, Hyaline Droplet		1 (2%)				
Calculus Micro Observation Only	5 (9%)	2 (4%)	4 (8%)	1 (2%)	2 (4%)	3 (6%)
Cyst				1 (2%)	2 (4%)	1 (2%)
Fibrosis						1 (2%)
Hemorrhage					1 (2%)	
Inflammation, Chronic Active					1 (2%)	1 (2%)
Inflammation, Suppurative	2 (4%)	1 (2%)	1 (2%)	3 (6%)	2 (4%)	2 (4%)
Mineralization	37 (70%)	45 (85%)	42 (79%)	43 (83%)	43 (81%)	31 (58%)
Necrosis					2 (4%)	
Nephropathy	34 (64%)	39 (74%)	35 (66%)	42 (81%)	36 (68%)	45 (85%)
Pigmentation	2 (4%)					
Artery, Inflammation, Chronic Active				1 (2%)	1 (2%)	
Capsule, Hemorrhage	1 (2%)					
Pelvis, Dilatation		1 (2%)			2 (4%)	1 (2%)
Pelvis, Inflammation	1 (2%)	1 (2%)			5 (9%)	1 (2%)
Renal Tubule, Dilatation			1 (2%)			
Renal Tubule, Hyperplasia			1 (2%)			
Renal Tubule, Necrosis		1 (2%)				
Renal Tubule, Nephropathy						1 (2%)
Transitional Epithelium, Hyperplasia	2 (4%)	2 (4%)	1 (2%)	2 (4%)	6 (11%)	5 (9%)
Urinary Bladder	(53)	(52)	(53)	(53)	(51)	(53)
Infiltration Cellular, Lymphoid						1 (2%)
Inflammation	2 (4%)	3 (6%)	1 (2%)	1 (2%)	6 (12%)	1 (2%)
Transitional Epithelium, Hyperplasia		1 (2%)			4 (8%)	4 (8%)
Transitional Epithelium, Metaplasia, Squamous					1 (2%)	

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

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
DISPOSITION SUMMARY	
Animals Initially In Study	50
Early Deaths	
Moribund Sacrifice	25
Natural Death	10
Survivors	
Terminal Sacrifice	15
Animals Examined Microscopically	50
ALIMENTARY SYSTEM	
Intestine Large, Rectum	(50)
Parasite Metazoan	2 (4%)
Liver	(50)
Angiectasis	1 (2%)
Basophilic Focus	9 (18%)
Basophilic Focus, Multiple	4 (8%)
Cholangiofibrosis	3 (6%)
Clear Cell Focus	4 (8%)
Clear Cell Focus, Multiple	2 (4%)
Degeneration, Cystic	1 (2%)
Eosinophilic Focus	8 (16%)
Eosinophilic Focus, Multiple	14 (28%)
Fatty Change, Diffuse	6 (12%)
Fatty Change, Focal	7 (14%)
Hematopoietic Cell Proliferation	31 (62%)
Hepatodiaphragmatic Nodule	1 (2%)
Inflammation	48 (96%)
Mixed Cell Focus	5 (10%)
Mixed Cell Focus, Multiple	19 (38%)
Necrosis	11 (22%)
Pigmentation	48 (96%)
Toxic Hepatopathy	9 (18%)
Bile Duct, Cyst	2 (4%)
Bile Duct, Fibrosis	1 (2%)
Bile Duct, Hyperplasia	1 (2%)
Centrilobular, Degeneration	7 (14%)
Hepatocyte, Hypertrophy	14 (28%)
Hepatocyte, Multinucleated	25 (50%)
Oval Cell, Hyperplasia	3 (6%)
Mesentery	(2)

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

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
ALIMENTARY SYSTEM - CONT	
Inflammation, Chronic Active	1 (50%)
Necrosis	1 (50%)
Oral Mucosa	(50)
Gingival, Hyperplasia, Squamous	14 (28%)
Pancreas	(49)
Acinus, Vacuolization Cytoplasmic	2 (4%)
Artery, Inflammation, Chronic Active	1 (2%)
Stomach, Forestomach	(50)
Erosion	1 (2%)
Hyperkeratosis	1 (2%)
Hyperplasia, Squamous	5 (10%)
Inflammation	1 (2%)
Ulcer	1 (2%)
Stomach, Glandular	(50)
Mineralization	3 (6%)
Tooth	(24)
Peridontal Tissue, Inflammation	24 (100%)
CARDIOVASCULAR SYSTEM	
Heart	(50)
Cardiomyopathy	13 (26%)
ENDOCRINE SYSTEM	
Adrenal Cortex	(48)
Angiectasis	29 (60%)
Degeneration, Cystic	12 (25%)
Hyperplasia	7 (15%)
Hypertrophy	36 (75%)
Necrosis	3 (6%)
Vacuolization Cytoplasmic	10 (21%)
Bilateral, Inflammation, Chronic Active	1 (2%)
Adrenal Medulla	(48)
Hyperplasia	7 (15%)
Parathyroid Gland	(47)
Fibrosis	1 (2%)
Pituitary Gland	(49)
Angiectasis	13 (27%)
Cyst	1 (2%)
Cytoplasmic Alteration	2 (4%)

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

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
ENDOCRINE SYSTEM - CONT	
Vacuolization Cytoplasmic	2 (4%)
Pars Distalis, Hyperplasia	19 (39%)
Thyroid Gland	(48)
C-Cell, Hyperplasia	15 (31%)
Follicular Cell, Hypertrophy	23 (48%)
GENERAL BODY SYSTEM	
None	
GENITAL SYSTEM	
Clitoral Gland	(50)
Inflammation	48 (96%)
Duct, Cyst	39 (78%)
Ovary	(47)
Atrophy	39 (83%)
Cyst	12 (26%)
Uterus	(49)
Congestion	1 (2%)
Hemorrhage	1 (2%)
Inflammation, Chronic Active	7 (14%)
Inflammation, Suppurative	3 (6%)
Metaplasia, Squamous	28 (57%)
Endometrium, Hyperplasia, Cystic	35 (71%)
HEMATOPOIETIC SYSTEM	
Bone Marrow	(50)
Hyperplasia	43 (86%)
Lymph Node	(3)
Iliac, Ectasia	1 (33%)
Iliac, Hyperplasia, Plasma Cell	1 (33%)
Lumbar, Ectasia	1 (33%)
Lumbar, Hyperplasia, Plasma Cell	1 (33%)
Renal, Ectasia	1 (33%)
Renal, Hyperplasia, Plasma Cell	1 (33%)
Lymph Node, Mandibular	(49)
Ectasia	1 (2%)
Hyperplasia, Lymphoid	1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
HEMATOPOIETIC SYSTEM - CONT	
Hyperplasia, Plasma Cell	29 (59%)
Spleen	(49)
Hematopoietic Cell Proliferation	49 (100%)
Pigmentation	48 (98%)
Lymphoid Follicle, Atrophy	2 (4%)
Thymus	(49)
Atrophy	44 (90%)
Hemorrhage	1 (2%)
INTEGUMENTARY SYSTEM	
Mammary Gland	(50)
Cyst	3 (6%)
Hyperplasia	19 (38%)
Inflammation	1 (2%)
Inflammation, Granulomatous	1 (2%)
Skin	(50)
Hyperkeratosis	1 (2%)
Lip, Inflammation, Chronic Active	1 (2%)
MUSCULOSKELETAL SYSTEM	
Bone	(50)
Osteopetrosis	1 (2%)
NERVOUS SYSTEM	
Brain	(49)
Mineralization	1 (2%)
RESPIRATORY SYSTEM	
Lung	(50)
Congestion	1 (2%)
Hemorrhage	2 (4%)
Infiltration Cellular, Histiocyte	30 (60%)
Inflammation	5 (10%)
Metaplasia, Squamous	1 (2%)
Mineralization	1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
RESPIRATORY SYSTEM - CONT	
Alveolar Epithelium, Hyperplasia	6 (12%)
Alveolar Epithelium, Metaplasia, Bronchiolar	7 (14%)
Nose	(50)
Inflammation	7 (14%)
Nasolacrimal Duct, Inflammation	1 (2%)
Respiratory Epithelium, Hyperplasia	2 (4%)
Trachea	(50)
Inflammation	1 (2%)
SPECIAL SENSES SYSTEM	
Eye	(49)
Retina, Atrophy	1 (2%)
Harderian Gland	(49)
Inflammation	6 (12%)
URINARY SYSTEM	
Kidney	(48)
Accumulation, Hyaline Droplet	3 (6%)
Calculus Micro Observation Only	1 (2%)
Infarct	1 (2%)
Inflammation	1 (2%)
Inflammation, Suppurative	2 (4%)
Mineralization	41 (85%)
Nephropathy	35 (73%)
Pelvis, Dilatation	1 (2%)
Pelvis, Inflammation	1 (2%)
Transitional Epithelium, Hyperplasia	3 (6%)
Urinary Bladder	(50)
Inflammation	2 (4%)
Transitional Epithelium, Hyperplasia	3 (6%)

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

END OF REPORT

FINAL #2 RATS

Facility: Battelle Columbus Laboratory

Chemical CAS #: 57117-31-4

Lock Date: 07/25/02

Cage Range: All

Reasons For Removal:	25018 Dosing Accident	25019 Moribund Sacrifice
	25020 Natural Death	25021 Terminal Sacrifice

Removal Date Range: All

Treatment Groups: Include All

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
DISPOSITION SUMMARY						
Animals Initially in Study	98	98	98	98	98	98
Early Deaths						
Natural Death	7	10	10	8	14	11
Moribund Sacrifice	21	20	17	19	19	19
Dosing Accident		1	2	1		
Survivors						
Terminal Sacrifice	25	22	24	25	20	23
Animals Examined Microscopically	53	53	53	53	53	53
ALIMENTARY SYSTEM						
Intestine Large, Colon	(53)	(53)	(53)	(53)	(51)	(53)
Carcinoma, Metastatic, Uterus				1 (2%)		
Intestine Large, Rectum	(53)	(53)	(53)	(53)	(52)	(53)
Carcinoma, Metastatic, Uterus						1 (2%)
Intestine Large, Cecum	(53)	(53)	(53)	(52)	(51)	(53)
Intestine Small, Duodenum	(53)	(53)	(53)	(53)	(52)	(53)
Carcinoma, Metastatic, Uterus						1 (2%)
Intestine Small, Jejunum	(53)	(53)	(53)	(52)	(52)	(53)
Leiomyoma						1 (2%)
Liver	(53)	(53)	(53)	(52)	(53)	(53)
Carcinoma, Metastatic, Uterus					1 (2%)	1 (2%)
Cholangiocarcinoma				1 (2%)	1 (2%)	1 (2%)
Cholangiocarcinoma, Multiple						1 (2%)
Hepatocellular Adenoma	1 (2%)		1 (2%)		1 (2%)	3 (6%)
Oral Mucosa	(52)	(53)	(52)	(53)	(53)	(53)
Gingival, Squamous Cell Carcinoma	1 (2%)	2 (4%)	1 (2%)		1 (2%)	3 (6%)
Pancreas	(53)	(53)	(53)	(52)	(52)	(52)
Carcinoma, Metastatic, Uterus					1 (2%)	1 (2%)
Acinus, Adenoma					1 (2%)	
Acinus, Carcinoma					1 (2%)	
Stomach, Forestomach	(53)	(53)	(53)	(53)	(52)	(53)
Fibrosarcoma						1 (2%)
Stomach, Glandular	(53)	(53)	(53)	(53)	(52)	(53)
Carcinoma, Metastatic, Uterus						1 (2%)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
CARDIOVASCULAR SYSTEM						
Heart	(53)	(53)	(52)	(53)	(53)	(52)
Schwannoma Malignant	1 (2%)	2 (4%)		2 (4%)		
ENDOCRINE SYSTEM						
Adrenal Cortex	(53)	(53)	(53)	(52)	(53)	(53)
Adenoma	1 (2%)	1 (2%)			2 (4%)	
Carcinoma	1 (2%)				1 (2%)	
Adrenal Medulla	(53)	(53)	(53)	(52)	(53)	(53)
Pheochromocytoma Malignant			1 (2%)			
Pheochromocytoma Complex	1 (2%)					
Pheochromocytoma Benign	4 (8%)	5 (9%)	2 (4%)	5 (10%)	1 (2%)	2 (4%)
Bilateral, Pheochromocytoma Benign				1 (2%)		
Islets, Pancreatic	(53)	(53)	(53)	(52)	(52)	(52)
Adenoma			1 (2%)	1 (2%)	1 (2%)	2 (4%)
Carcinoma			1 (2%)			
Parathyroid Gland	(49)	(51)	(44)	(51)	(49)	(49)
Adenoma		2 (4%)				
Pituitary Gland	(53)	(53)	(53)	(53)	(53)	(53)
Carcinoma		1 (2%)				
Pars Distalis, Adenoma	15 (28%)	21 (40%)	23 (43%)	23 (43%)	21 (40%)	16 (30%)
Thyroid Gland	(53)	(53)	(51)	(53)	(51)	(51)
Bilateral, C-Cell, Adenoma		1 (2%)	1 (2%)	1 (2%)		
C-Cell, Adenoma	13 (25%)	9 (17%)	8 (16%)	8 (15%)	6 (12%)	7 (14%)
C-Cell, Carcinoma	2 (4%)	2 (4%)	2 (4%)	2 (4%)		1 (2%)
Follicular Cell, Adenoma		1 (2%)				
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(53)	(51)	(53)	(53)	(50)	(53)
Adenoma			1 (2%)			
Carcinoma, Metastatic, Mammary Gland		1 (2%)				
Ovary	(53)	(53)	(53)	(52)	(52)	(53)
Cystadenoma		1 (2%)				
Granulosa Cell Tumor Malignant		1 (2%)				

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
GENITAL SYSTEM - cont						
Granulosa Cell Tumor Benign		1 (2%)	1 (2%)			
Luteoma	1 (2%)					
Sertoli Cell Tumor Malignant				1 (2%)		
Uterus	(53)	(53)	(53)	(52)	(52)	(53)
Adenoma	2 (4%)					
Carcinoma	1 (2%)	1 (2%)		1 (2%)	5 (10%)	2 (4%)
Fibroma	1 (2%)					
Leiomyoma				1 (2%)		
Polyp Stromal	8 (15%)	3 (6%)	5 (9%)	5 (10%)	6 (12%)	3 (6%)
Polyp Stromal, Multiple	1 (2%)				1 (2%)	1 (2%)
Schwannoma Malignant				1 (2%)		1 (2%)
Squamous Cell Carcinoma					1 (2%)	
Cervix, Polyp Stromal			1 (2%)			
Cervix, Sarcoma Stromal		1 (2%)				
Cervix, Schwannoma Malignant		1 (2%)				
Cervix, Squamous Cell Carcinoma			1 (2%)			
Vagina	(1)	(1)	(1)			
Polyp			1 (100%)			
Sarcoma Stromal		1 (100%)				
Squamous Cell Papilloma	1 (100%)					
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(53)	(53)	(53)	(53)	(53)
Lymph Node	(5)	(4)	(4)	(4)	(3)	(7)
Deep Cervical, Carcinoma, Metastatic, Thyroid Gland			1 (25%)			
Inguinal, Carcinoma, Metastatic, Mammary Gland						1 (14%)
Mediastinal, Carcinoma, Metastatic, Thyroid Gland			1 (25%)			
Lymph Node, Mandibular	(53)	(53)	(51)	(53)	(51)	(51)
Lymph Node, Mesenteric	(53)	(53)	(53)	(52)	(52)	(53)
Carcinoma, Metastatic, Uterus					1 (2%)	
Spleen	(53)	(53)	(53)	(52)	(52)	(51)
Carcinoma, Metastatic, Uterus						1 (2%)
Thymus	(53)	(49)	(50)	(52)	(49)	(51)
Osteosarcoma, Metastatic, Skin						1 (2%)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
INTEGUMENTARY SYSTEM						
Mammary Gland	(53)	(53)	(53)	(53)	(53)	(53)
Adenoma	1 (2%)	1 (2%)	2 (4%)		1 (2%)	
Carcinoma	5 (9%)	9 (17%)	11 (21%)	2 (4%)	5 (9%)	3 (6%)
Carcinoma, Multiple		3 (6%)	2 (4%)			
Fibroadenoma	24 (45%)	23 (43%)	23 (43%)	21 (40%)	22 (42%)	17 (32%)
Fibroadenoma, Multiple	10 (19%)	12 (23%)	7 (13%)	8 (15%)	12 (23%)	13 (25%)
Osteosarcoma, Metastatic, Skin						1 (2%)
Skin	(53)	(53)	(53)	(53)	(53)	(53)
Basal Cell Carcinoma					1 (2%)	
Fibroma		1 (2%)	1 (2%)	1 (2%)		1 (2%)
Fibrosarcoma			1 (2%)			
Fibrous Histiocytoma						1 (2%)
Keratoacanthoma						1 (2%)
Neural Crest Tumor						1 (2%)
Neurofibroma		1 (2%)				
Osteosarcoma						1 (2%)
Schwannoma Malignant		1 (2%)				
Subcutaneous Tissue, Hemangioma				1 (2%)		
MUSCULOSKELETAL SYSTEM						
Bone	(53)	(53)	(53)	(53)	(53)	(53)
Osteosarcoma		1 (2%)				
Skeletal Muscle				(2)		
Rhabdomyosarcoma				1 (50%)		
NERVOUS SYSTEM						
Brain	(53)	(53)	(53)	(53)	(53)	(53)
Astrocytoma Malignant			1 (2%)		1 (2%)	1 (2%)
Carcinoma, Metastatic, Pituitary Gland		1 (2%)				
Granular Cell Tumor Malignant				1 (2%)		
Cranial Nerve, Squamous Cell Carcinoma, Metastatic, Oral Mucosa					1 (2%)	

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
RESPIRATORY SYSTEM						
Lung	(53)	(53)	(53)	(53)	(53)	(52)
Alveolar/Bronchiolar Adenoma						1 (2%)
Carcinoma, Metastatic, Mammary Gland	1 (2%)				1 (2%)	2 (4%)
Carcinoma, Metastatic, Thyroid Gland	1 (2%)		1 (2%)			
Carcinoma, Metastatic, Uterus					1 (2%)	1 (2%)
Cystic Keratinizing Epithelioma, Multiple						1 (2%)
Fibrous Histiocytoma, Metastatic, Skin						1 (2%)
Histiocytic Sarcoma						1 (2%)
Osteosarcoma, Metastatic, Skin						1 (2%)
Nose	(53)	(53)	(53)	(53)	(53)	(53)
Sarcoma			1 (2%)			
SPECIAL SENSES SYSTEM						
Eye	(53)	(53)	(52)	(53)	(52)	(52)
Sarcoma						1 (2%)
Harderian Gland	(53)	(53)	(53)	(53)	(52)	(52)
Carcinoma, Metastatic, Oral Mucosa		1 (2%)				
Zymbal's Gland					(1)	
Adenoma					1 (100%)	
URINARY SYSTEM						
Kidney	(53)	(53)	(53)	(52)	(53)	(53)
Lipoma	1 (2%)					
Nephroblastoma			1 (2%)		1 (2%)	
Renal Tubule, Adenoma			1 (2%)		1 (2%)	
Urinary Bladder	(53)	(52)	(53)	(53)	(51)	(53)
Carcinoma, Metastatic, Uterus					1 (2%)	
SYSTEMIC LESIONS						
Multiple Organs	*(53)	*(53)	*(53)	*(53)	*(53)	*(53)
Histiocytic Sarcoma						1 (2%)
Leukemia Mononuclear	1 (2%)	1 (2%)				1 (2%)
Lymphoma Malignant				1 (2%)		

* Number of animals with any tissue examined microscopically

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
TUMOR SUMMARY						
Total Animals with Primary Neoplasms (b)	48	49	49	44	48	46
Total Primary Neoplasms	97	110	102	89	95	89
Total Animals with Benign Neoplasms	45	45	43	42	45	41
Total Benign Neoplasms	84	83	79	76	77	69
Total Animals with Malignant Neoplasms	12	20	21	13	16	16
Total Malignant Neoplasms	13	27	23	13	18	19
Total Animals with Metastatic Neoplasms	2	3	1	1	3	5
Total Metastatic Neoplasm	2	3	3	1	7	14
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

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
DISPOSITION SUMMARY	
Animals Initially in Study	50
Early Deaths	
Moribund Sacrifice	25
Natural Death	10
Survivors	
Terminal Sacrifice	15
Animals Examined Microscopically	50
ALIMENTARY SYSTEM	
Intestine Large, Rectum	(50)
Squamous Cell Carcinoma, Metastatic, Uterus	1 (2%)
Oral Mucosa	(50)
Gingival, Squamous Cell Carcinoma	3 (6%)
Pancreas	(49)
Adenoma	1 (2%)
Carcinoma	1 (2%)
Stomach, Forestomach	(50)
Squamous Cell Papilloma	1 (2%)
CARDIOVASCULAR SYSTEM	
None	
ENDOCRINE SYSTEM	
Adrenal Cortex	(48)
Adenoma	1 (2%)
Adrenal Medulla	(48)
Pheochromocytoma Benign	1 (2%)
Pituitary Gland	(49)
Pars Distalis, Adenoma	13 (27%)
Thyroid Gland	(48)
C-Cell, Adenoma	5 (10%)

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
GENERAL BODY SYSTEM	
None	
GENITAL SYSTEM	
Ovary	(47)
Luteoma	1 (2%)
Uterus	(49)
Carcinoma	1 (2%)
Hemangioma	1 (2%)
Polyp Stromal	4 (8%)
Cervix, Squamous Cell Carcinoma	1 (2%)
HEMATOPOIETIC SYSTEM	
Thymus	(49)
Thymoma Malignant, Metastatic, Mammary Gland	1 (2%)
INTEGUMENTARY SYSTEM	
Mammary Gland	(50)
Adenoma	2 (4%)
Carcinoma	5 (10%)
Fibroadenoma	25 (50%)
Fibroadenoma, Multiple	9 (18%)
Skin	(50)
Basal Cell Carcinoma	1 (2%)
Fibroma	1 (2%)
Fibrosarcoma	1 (2%)
Sarcoma	1 (2%)
MUSCULOSKELETAL SYSTEM	
Bone	(50)
Fibrosarcoma, Metastatic, Skin	1 (2%)

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

Lung	(50)
Squamous Cell Carcinoma, Metastatic, Uterus	1 (2%)

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
TUMOR SUMMARY	
Total Animals with Primary Neoplasms (b)	43
Total Primary Neoplasms	79
Total Animals with Benign Neoplasms	40
Total Benign Neoplasms	65
Total Animals with Malignant Neoplasms	12
Total Malignant Neoplasms	14
Total Animals with Metastatic Neoplasms	3
Total Metastatic Neoplasm	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

END OF REPORT

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION(PECDF)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

FINAL #2 RATS CONTROL VS TREATED

REASONS FOR REMOVAL:
25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:
INCLUDE 001 0 NG/KG
INCLUDE 002 6 NG/KG
INCLUDE 003 20 NG/KG
INCLUDE 004 44 NG/KG
INCLUDE 005 92 NG/KG
INCLUDE 006 200 NG/KG

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 05
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD
Rats(SPRAGUE-DAWLEY)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION(PECDF)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/23/03
TIME: 10:50:31

NTP C#: 96007F
CAS: 57117-31-4

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
Nose
Ovary
Pancreas
Parathyroid Gland
Pituitary Gland
Thyroid Gland

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 05
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION(PECDF)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/23/03
TIME: 10:50:31

NTP C#: 96007F
CAS: 57117-31-4

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TOXIC EQUIVALENCY FACTOR EVALUATION(

Female Rats

Organ	Morphology
Liver	Cholangiocarcinoma
	Hepatocellular Adenoma
Mammary Gland	Carcinoma
	Carcinoma or Adenoma
Pituitary Gland: Pars Distalis or Unspecified Site	
	Adenoma
	Carcinoma or Adenoma
Thyroid Gland: C-Cell	Carcinoma or Adenoma
Uterus	Adenoma
All Organs	Malignant Tumors

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Adrenal Cortex Adenoma						
TUMOR RATES						
OVERALL (a)	1/53 (2%)	1/53 (2%)	0/53 (0%)	0/52 (0%)	2/53 (4%)	0/53 (0%)
POLY-3 RATE (b)	1/41.78	1/38.07	0/36.67	0/37.91	2/36.31	0/36.61
POLY-3 PERCENT (g)	2.4%	2.6%	0.0%	0.0%	5.5%	0.0%
TERMINAL (d)	1/25 (4%)	1/22 (5%)	0/24 (0%)	0/25 (0%)	1/20 (5%)	0/23 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---	---	681	---
STATISTICAL TESTS						
LIFE TABLE	P=0.525N	P=0.734	P=0.508N	P=0.500N	P=0.432	P=0.517N
POLY 3	P=0.522N	P=0.740	P=0.526N	P=0.519N	P=0.451	P=0.526N
POLY 1.5	P=0.514N	P=0.748	P=0.520N	P=0.512N	P=0.464	P=0.517N
POLY 6	P=0.529N	P=0.731	P=0.531N	P=0.528N	P=0.445	P=0.535N
LOGISTIC REGRESSION	P=0.535N	P=0.734	(e)	(e)	P=0.441	(e)
COCH-ARM / FISHERS	P=0.507N	P=0.752N	P=0.500N	P=0.505N	P=0.500	P=0.500N
ORDER RESTRICTED	P=0.356N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Adrenal Medulla Pheochromocytoma Benign						
TUMOR RATES						
OVERALL (a)	4/53 (8%)	5/53 (9%)	2/53 (4%)	6/52 (12%)	1/53 (2%)	2/53 (4%)
POLY-3 RATE (b)	4/42.04	5/38.67	2/36.78	6/37.91	1/36.13	2/36.98
POLY-3 PERCENT (g)	9.5%	12.9%	5.4%	15.8%	2.8%	5.4%
TERMINAL (d)	3/25 (12%)	2/22 (9%)	1/24 (4%)	6/25 (24%)	1/20 (5%)	1/23 (4%)
FIRST INCIDENCE	659	651	701	728 (T)	728 (T)	624
STATISTICAL TESTS						
LIFE TABLE	P=0.167N	P=0.405	P=0.377N	P=0.352	P=0.244N	P=0.399N
POLY 3	P=0.164N	P=0.447	P=0.400N	P=0.304	P=0.227N	P=0.397N
POLY 1.5	P=0.154N	P=0.468	P=0.384N	P=0.330	P=0.213N	P=0.375N
POLY 6	P=0.173N	P=0.428	P=0.412N	P=0.274	P=0.236N	P=0.418N
LOGISTIC REGRESSION	P=0.171N	P=0.420	P=0.411N	P=0.276	P=0.231N	P=0.411N
COCH-ARM / FISHERS	P=0.138N	P=0.500	P=0.339N	P=0.359	P=0.181N	P=0.339N
ORDER RESTRICTED	P=0.226N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Adrenal Medulla						
Pheochromocytoma: Benign, Complex, Malignant, NOS						
TUMOR RATES						
OVERALL (a)	5/53 (9%)	5/53 (9%)	3/53 (6%)	6/52 (12%)	1/53 (2%)	2/53 (4%)
POLY-3 RATE (b)	5/42.04	5/38.67	3/36.78	6/37.91	1/36.13	2/36.98
POLY-3 PERCENT (g)	11.9%	12.9%	8.2%	15.8%	2.8%	5.4%
TERMINAL (d)	4/25 (16%)	2/22 (9%)	2/24 (8%)	6/25 (24%)	1/20 (5%)	1/23 (4%)
FIRST INCIDENCE	659	651	701	728 (T)	728 (T)	624
STATISTICAL TESTS						
LIFE TABLE	P=0.108N	P=0.531	P=0.396N	P=0.486	P=0.154N	P=0.270N
POLY 3	P=0.105N	P=0.578	P=0.431N	P=0.427	P=0.139N	P=0.270N
POLY 1.5	P=0.098N	P=0.598	P=0.412N	P=0.456	P=0.128N	P=0.250N
POLY 6	P=0.111N	P=0.558	P=0.446N	P=0.392	P=0.146N	P=0.288N
LOGISTIC REGRESSION	P=0.110N	P=0.546	P=0.447N	P=0.397	P=0.143N	P=0.287N
COCH-ARM / FISHERS	P=0.087N	P=0.629N	P=0.358N	P=0.486	P=0.103N	P=0.219N
ORDER RESTRICTED	P=0.175N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Heart						
Schwannoma Malignant						
TUMOR RATES						
OVERALL (a)	1/53 (2%)	2/53 (4%)	0/52 (0%)	2/53 (4%)	0/53 (0%)	0/52 (0%)
POLY-3 RATE (b)	1/41.78	2/38.22	0/36.03	2/39.15	0/36.13	0/36.44
POLY-3 PERCENT (g)	2.4%	5.2%	0.0%	5.1%	0.0%	0.0%
TERMINAL (d)	1/25 (4%)	1/22 (5%)	0/24 (0%)	1/25 (4%)	0/20 (0%)	0/23 (0%)
FIRST INCIDENCE	728 (T)	689	---	302	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.179N	P=0.454	P=0.508N	P=0.502	P=0.545N	P=0.517N
POLY 3	P=0.185N	P=0.469	P=0.529N	P=0.477	P=0.529N	P=0.527N
POLY 1.5	P=0.179N	P=0.481	P=0.523N	P=0.489	P=0.521N	P=0.519N
POLY 6	P=0.190N	P=0.456	P=0.533N	P=0.463	P=0.533N	P=0.535N
LOGISTIC REGRESSION	P=0.173N	P=0.443	(e)	P=0.518	(e)	(e)
COCH-ARM / FISHERS	P=0.171N	P=0.500	P=0.505N	P=0.500	P=0.500N	P=0.505N
ORDER RESTRICTED	P=0.220N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Islets, Pancreatic Adenoma						
TUMOR RATES						
OVERALL (a)	0/53 (0%)	0/53 (0%)	1/53 (2%)	1/52 (2%)	1/52 (2%)	2/52 (4%)
POLY-3 RATE (b)	0/41.78	0/38.07	1/36.67	1/37.91	1/35.47	2/36.44
POLY-3 PERCENT (g)	0.0%	0.0%	2.7%	2.6%	2.8%	5.5%
TERMINAL (d)	0/25 (0%)	0/22 (0%)	1/24 (4%)	1/25 (4%)	0/20 (0%)	2/23 (9%)
FIRST INCIDENCE	---	---	728 (T)	728 (T)	721	728 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.087	(e)	P=0.492	P=0.500	P=0.476	P=0.219
POLY 3	P=0.082	(e)	P=0.474	P=0.481	P=0.467	P=0.207
POLY 1.5	P=0.086	(e)	P=0.480	P=0.488	P=0.475	P=0.217
POLY 6	P=0.078	(e)	P=0.469	P=0.472	P=0.464	P=0.199
LOGISTIC REGRESSION	P=0.086	(e)	P=0.492	P=0.500	P=0.464	P=0.219
COCH-ARM / FISHERS	P=0.094	(e)	P=0.500	P=0.495	P=0.495	P=0.243
ORDER RESTRICTED	P=0.075	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Islets, Pancreatic Carcinoma or Adenoma						
TUMOR RATES						
OVERALL (a)	0/53 (0%)	0/53 (0%)	2/53 (4%)	1/52 (2%)	1/52 (2%)	2/52 (4%)
POLY-3 RATE (b)	0/41.78	0/38.07	2/36.67	1/37.91	1/35.47	2/36.44
POLY-3 PERCENT (g)	0.0%	0.0%	5.5%	2.6%	2.8%	5.5%
TERMINAL (d)	0/25 (0%)	0/22 (0%)	2/24 (8%)	1/25 (4%)	0/20 (0%)	2/23 (9%)
FIRST INCIDENCE	---	---	728 (T)	728 (T)	721	728 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.156	(e)	P=0.228	P=0.500	P=0.476	P=0.219
POLY 3	P=0.143	(e)	P=0.209	P=0.481	P=0.467	P=0.207
POLY 1.5	P=0.151	(e)	P=0.216	P=0.488	P=0.475	P=0.217
POLY 6	P=0.137	(e)	P=0.204	P=0.472	P=0.464	P=0.199
LOGISTIC REGRESSION	P=0.154	(e)	P=0.228	P=0.500	P=0.464	P=0.219
COCH-ARM / FISHERS	P=0.166	(e)	P=0.248	P=0.495	P=0.495	P=0.243
ORDER RESTRICTED	P=0.101	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Liver Cholangiocarcinoma						
TUMOR RATES						
OVERALL (a)	0/53 (0%)	0/53 (0%)	0/53 (0%)	1/52 (2%)	1/53 (2%)	2/53 (4%)
POLY-3 RATE (b)	0/41.78	0/38.07	0/36.67	1/37.91	1/36.13	2/37.02
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	2.6%	2.8%	5.4%
TERMINAL (d)	0/25 (0%)	0/22 (0%)	0/24 (0%)	1/25 (4%)	1/20 (5%)	1/23 (4%)
FIRST INCIDENCE	---	---	---	728 (T)	728 (T)	608
STATISTICAL TESTS						
LIFE TABLE	P=0.034 *	(e)	(e)	P=0.500	P=0.455	P=0.201
POLY 3	P=0.036 *	(e)	(e)	P=0.481	P=0.471	P=0.211
POLY 1.5	P=0.038 *	(e)	(e)	P=0.488	P=0.479	P=0.220
POLY 6	P=0.035 *	(e)	(e)	P=0.472	P=0.467	P=0.203
LOGISTIC REGRESSION	P=0.034 *	(e)	(e)	P=0.500	P=0.455	P=0.219
COCH-ARM / FISHERS	P=0.041 *	(e)	(e)	P=0.495	P=0.500	P=0.248
ORDER RESTRICTED	P=0.047 *	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Liver Hepatocellular Adenoma						
TUMOR RATES						
OVERALL (a)	1/53 (2%)	0/53 (0%)	1/53 (2%)	0/52 (0%)	1/53 (2%)	3/53 (6%)
POLY-3 RATE (b)	1/41.97	0/38.07	1/36.67	0/37.91	1/36.13	3/36.61
POLY-3 PERCENT (g)	2.4%	0.0%	2.7%	0.0%	2.8%	8.2%
TERMINAL (d)	0/25 (0%)	0/22 (0%)	1/24 (4%)	0/25 (0%)	1/20 (5%)	3/23 (13%)
FIRST INCIDENCE	678	---	728 (T)	---	728 (T)	728 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.034 *	P=0.546N	P=0.726	P=0.554N	P=0.705	P=0.264
POLY 3	P=0.035 *	P=0.519N	P=0.730	P=0.520N	P=0.727	P=0.257
POLY 1.5	P=0.037 *	P=0.512N	P=0.738	P=0.512N	P=0.736	P=0.275
POLY 6	P=0.034 *	P=0.528N	P=0.724	P=0.530N	P=0.721	P=0.240
LOGISTIC REGRESSION	P=0.031 *	P=0.514N	P=0.730	P=0.515N	P=0.727	P=0.239
COCH-ARM / FISHERS	P=0.040 *	P=0.500N	P=0.752N	P=0.505N	P=0.752N	P=0.309
ORDER RESTRICTED	P=0.037 *	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Mammary Gland Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	1/53 (2%)	2/53 (4%)	0/53 (0%)	1/53 (2%)	0/53 (0%)
POLY-3 RATE (b)	1/41.78	1/38.07	2/36.67	0/38.22	1/36.13	0/36.61
POLY-3 PERCENT (g)	2.4%	2.6%	5.5%	0.0%	2.8%	0.0%
TERMINAL (d)	1/25 (4%)	1/22 (5%)	2/24 (8%)	0/25 (0%)	1/20 (5%)	0/23 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	728 (T)	---	728 (T)	---
STATISTICAL TESTS						
LIFE TABLE	P=0.254N	P=0.734	P=0.486	P=0.500N	P=0.712	P=0.517N
POLY 3	P=0.261N	P=0.740	P=0.455	P=0.518N	P=0.728	P=0.526N
POLY 1.5	P=0.255N	P=0.748	P=0.466	P=0.509N	P=0.737	P=0.517N
POLY 6	P=0.266N	P=0.731	P=0.446	P=0.527N	P=0.723	P=0.535N
LOGISTIC REGRESSION	P=0.254N	P=0.734	P=0.486	(e)	P=0.712	(e)
COCH-ARM / FISHERS	P=0.239N	P=0.752N	P=0.500	P=0.500N	P=0.752N	P=0.500N
ORDER RESTRICTED	P=0.263N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Mammary Gland Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	5/53 (9%)	12/53 (23%)	13/53 (25%)	2/53 (4%)	5/53 (9%)	3/53 (6%)
POLY-3 RATE (b)	5/42.44	12/40.22	13/40.44	2/38.22	5/37.02	3/38.06
POLY-3 PERCENT (g)	11.8%	29.8%	32.2%	5.2%	13.5%	7.9%
TERMINAL (d)	3/25 (12%)	6/22 (27%)	7/24 (29%)	2/25 (8%)	4/20 (20%)	1/23 (4%)
FIRST INCIDENCE	619	420	219	728 (T)	348	443
STATISTICAL TESTS						
LIFE TABLE	P=0.026N*	P=0.034 *	P=0.028 *	P=0.247N	P=0.505	P=0.430N
POLY 3	P=0.021N*	P=0.036 *	P=0.021 *	P=0.259N	P=0.543	P=0.417N
POLY 1.5	P=0.019N*	P=0.042 *	P=0.024 *	P=0.238N	P=0.568	P=0.395N
POLY 6	P=0.024N*	P=0.030 *	P=0.018 *	P=0.286N	P=0.524	P=0.440N
LOGISTIC REGRESSION	P=0.018N*	P=0.040 *	P=0.035 *	P=0.267N	P=0.567	P=0.362N
COCH-ARM / FISHERS	P=0.016N*	P=0.055	P=0.034 *	P=0.219N	P=0.629N	P=0.358N
ORDER RESTRICTED	P=0.028N*	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Mammary Gland Carcinoma or Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	6/53 (11%)	13/53 (25%)	14/53 (26%)	2/53 (4%)	6/53 (11%)	3/53 (6%)
POLY-3 RATE (b)	6/42.44	13/40.22	14/40.44	2/38.22	6/37.02	3/38.06
POLY-3 PERCENT (g)	14.1%	32.3%	34.6%	5.2%	16.2%	7.9%
TERMINAL (d)	4/25 (16%)	7/22 (32%)	8/24 (33%)	2/25 (8%)	5/20 (25%)	1/23 (4%)
FIRST INCIDENCE	619	420	219	728 (T)	348	443
STATISTICAL TESTS						
LIFE TABLE	P=0.016N*	P=0.037 *	P=0.031 *	P=0.155N	P=0.477	P=0.310N
POLY 3	P=0.012N*	P=0.040 *	P=0.024 *	P=0.167N	P=0.522	P=0.297N
POLY 1.5	P=0.011N*	P=0.048 *	P=0.027 *	P=0.150N	P=0.551	P=0.276N
POLY 6	P=0.014N*	P=0.034 *	P=0.021 *	P=0.190N	P=0.501	P=0.318N
LOGISTIC REGRESSION	P=0.011N*	P=0.042 *	P=0.037 *	P=0.177N	P=0.535	P=0.258N
COCH-ARM / FISHERS	P=0.010N*	P=0.064	P=0.040 *	P=0.135N	P=0.620N	P=0.244N
ORDER RESTRICTED	P=0.014N*	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Mammary Gland Fibroadenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	34/53 (64%)	35/53 (66%)	30/53 (57%)	29/53 (55%)	34/53 (64%)	30/53 (57%)
POLY-3 RATE (b)	34/49.74	35/46.94	30/42.83	29/46.77	34/45.32	30/43.49
POLY-3 PERCENT (g)	68.4%	74.6%	70.0%	62.0%	75.0%	69.0%
TERMINAL (d)	14/25 (56%)	13/22 (59%)	15/24 (63%)	11/25 (44%)	13/20 (65%)	15/23 (65%)
FIRST INCIDENCE	289	289	393	302	321	326
STATISTICAL TESTS						
LIFE TABLE	P=0.513	P=0.263	P=0.530N	P=0.428N	P=0.226	P=0.549
POLY 3	P=0.536	P=0.321	P=0.521	P=0.325N	P=0.307	P=0.565
POLY 1.5	P=0.447N	P=0.387	P=0.565N	P=0.271N	P=0.367	P=0.490N
POLY 6	P=0.436	P=0.277	P=0.467	P=0.383N	P=0.283	P=0.448
LOGISTIC REGRESSION	P=0.366N	P=0.487	P=0.406N	P=0.199N	P=0.503	P=0.348N
COCH-ARM / FISHERS	P=0.301N	P=0.500	P=0.276N	P=0.214N	P=0.580N	P=0.276N
ORDER RESTRICTED	P=0.616	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Mammary Gland Fibroma, Fibroadenoma or Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	35/53 (66%)	36/53 (68%)	30/53 (57%)	29/53 (55%)	35/53 (66%)	30/53 (57%)
POLY-3 RATE (b)	35/49.74	36/46.94	30/42.83	29/46.77	35/45.32	30/43.49
POLY-3 PERCENT (g)	70.4%	76.7%	70.0%	62.0%	77.2%	69.0%
TERMINAL (d)	15/25 (60%)	14/22 (64%)	15/24 (63%)	11/25 (44%)	14/20 (70%)	15/23 (65%)
FIRST INCIDENCE	289	289	393	302	321	326
STATISTICAL TESTS						
LIFE TABLE	P=0.502N	P=0.257	P=0.473N	P=0.374N	P=0.215	P=0.512N
POLY 3	P=0.482N	P=0.312	P=0.579N	P=0.251N	P=0.294	P=0.533N
POLY 1.5	P=0.386N	P=0.381	P=0.482N	P=0.204N	P=0.357	P=0.406N
POLY 6	P=0.500	P=0.265	P=0.555	P=0.302N	P=0.268	P=0.537
LOGISTIC REGRESSION	P=0.319N	P=0.475	P=0.336N	P=0.151N	P=0.482	P=0.282N
COCH-ARM / FISHERS	P=0.254N	P=0.500	P=0.213N	P=0.160N	P=0.581N	P=0.213N
ORDER RESTRICTED	P=0.561N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	38/53 (72%)	40/53 (75%)	37/53 (70%)	31/53 (58%)	38/53 (72%)	31/53 (58%)
POLY-3 RATE (b)	38/50.41	40/48.33	37/46.22	31/46.77	38/46.22	31/44.27
POLY-3 PERCENT (g)	75.4%	82.8%	80.1%	66.3%	82.2%	70.0%
TERMINAL (d)	16/25 (64%)	16/22 (73%)	18/24 (75%)	13/25 (52%)	16/20 (80%)	15/23 (65%)
FIRST INCIDENCE	289	289	219	302	321	326
STATISTICAL TESTS						
LIFE TABLE	P=0.300N	P=0.205	P=0.393	P=0.337N	P=0.199	P=0.417N
POLY 3	P=0.209N	P=0.249	P=0.376	P=0.215N	P=0.278	P=0.357N
POLY 1.5	P=0.138N	P=0.310	P=0.453	P=0.157N	P=0.352	P=0.244N
POLY 6	P=0.314N	P=0.201	P=0.316	P=0.293N	P=0.229	P=0.495N
LOGISTIC REGRESSION	P=0.086N	P=0.392	P=0.581	P=0.110N	P=0.477	P=0.152N
COCH-ARM / FISHERS	P=0.065N	P=0.413	P=0.500N	P=0.111N	P=0.585N	P=0.111N
ORDER RESTRICTED	P=0.228N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	2/53 (4%)	1/53 (2%)	0/53 (0%)	1/53 (2%)	3/53 (6%)
POLY-3 RATE (b)	1/41.78	2/38.16	1/37.31	0/38.22	1/36.17	3/36.83
POLY-3 PERCENT (g)	2.4%	5.2%	2.7%	0.0%	2.8%	8.1%
TERMINAL (d)	1/25 (4%)	1/22 (5%)	0/24 (0%)	0/25 (0%)	0/20 (0%)	2/23 (9%)
FIRST INCIDENCE	728 (T)	706	517	---	717	668
STATISTICAL TESTS						
LIFE TABLE	P=0.150	P=0.448	P=0.746	P=0.500N	P=0.722	P=0.264
POLY 3	P=0.149	P=0.468	P=0.735	P=0.518N	P=0.728	P=0.261
POLY 1.5	P=0.155	P=0.481	P=0.741	P=0.509N	P=0.737	P=0.277
POLY 6	P=0.143	P=0.455	P=0.732	P=0.527N	P=0.724	P=0.247
LOGISTIC REGRESSION	P=0.145	P=0.437	P=0.762N	(e)	P=0.725	P=0.240
COCH-ARM / FISHERS	P=0.167	P=0.500	P=0.752N	P=0.500N	P=0.752N	P=0.309
ORDER RESTRICTED	P=0.134	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	2/53 (4%)	1/53 (2%)	0/53 (0%)	1/53 (2%)	3/53 (6%)
POLY-3 RATE (b)	1/41.78	2/38.16	1/37.31	0/38.22	1/36.17	3/36.83
POLY-3 PERCENT (g)	2.4%	5.2%	2.7%	0.0%	2.8%	8.1%
TERMINAL (d)	1/25 (4%)	1/22 (5%)	0/24 (0%)	0/25 (0%)	0/20 (0%)	2/23 (9%)
FIRST INCIDENCE	728 (T)	706	517	---	717	668
STATISTICAL TESTS						
LIFE TABLE	P=0.150	P=0.448	P=0.746	P=0.500N	P=0.722	P=0.264
POLY 3	P=0.149	P=0.468	P=0.735	P=0.518N	P=0.728	P=0.261
POLY 1.5	P=0.155	P=0.481	P=0.741	P=0.509N	P=0.737	P=0.277
POLY 6	P=0.143	P=0.455	P=0.732	P=0.527N	P=0.724	P=0.247
LOGISTIC REGRESSION	P=0.145	P=0.437	P=0.762N	(e)	P=0.725	P=0.240
COCH-ARM / FISHERS	P=0.167	P=0.500	P=0.752N	P=0.500N	P=0.752N	P=0.309
ORDER RESTRICTED	P=0.134	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Oral Mucosa Squamous Cell Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	2/53 (4%)	1/53 (2%)	0/53 (0%)	1/53 (2%)	3/53 (6%)
POLY-3 RATE (b)	1/41.78	2/38.16	1/37.31	0/38.22	1/36.17	3/36.83
POLY-3 PERCENT (g)	2.4%	5.2%	2.7%	0.0%	2.8%	8.1%
TERMINAL (d)	1/25 (4%)	1/22 (5%)	0/24 (0%)	0/25 (0%)	0/20 (0%)	2/23 (9%)
FIRST INCIDENCE	728 (T)	706	517	---	717	668
STATISTICAL TESTS						
LIFE TABLE	P=0.150	P=0.448	P=0.746	P=0.500N	P=0.722	P=0.264
POLY 3	P=0.149	P=0.468	P=0.735	P=0.518N	P=0.728	P=0.261
POLY 1.5	P=0.155	P=0.481	P=0.741	P=0.509N	P=0.737	P=0.277
POLY 6	P=0.143	P=0.455	P=0.732	P=0.527N	P=0.724	P=0.247
LOGISTIC REGRESSION	P=0.145	P=0.437	P=0.762N	(e)	P=0.725	P=0.240
COCH-ARM / FISHERS	P=0.167	P=0.500	P=0.752N	P=0.500N	P=0.752N	P=0.309
ORDER RESTRICTED	P=0.134	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Ovary Granulosa Cell Tumor: Benign, Malignant, NOS						
TUMOR RATES						
OVERALL (a)	0/53 (0%)	2/53 (4%)	1/53 (2%)	0/52 (0%)	0/52 (0%)	0/53 (0%)
POLY-3 RATE (b)	0/41.78	2/38.36	1/36.67	0/37.91	0/35.44	0/36.61
POLY-3 PERCENT (g)	0.0%	5.2%	2.7%	0.0%	0.0%	0.0%
TERMINAL (d)	0/25 (0%)	1/22 (5%)	1/24 (4%)	0/25 (0%)	0/20 (0%)	0/23 (0%)
FIRST INCIDENCE	---	651	728 (T)	---	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.230N	P=0.208	P=0.492	(e)	(e)	(e)
POLY 3	P=0.238N	P=0.218	P=0.474	(e)	(e)	(e)
POLY 1.5	P=0.231N	P=0.226	P=0.480	(e)	(e)	(e)
POLY 6	P=0.243N	P=0.211	P=0.469	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.229N	P=0.216	P=0.492	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.215N	P=0.248	P=0.500	(e)	(e)	(e)
ORDER RESTRICTED	P=0.279N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Pancreas Carcinoma or Adenoma						
TUMOR RATES						
OVERALL (a)	0/53 (0%)	0/53 (0%)	0/53 (0%)	0/52 (0%)	2/52 (4%)	0/52 (0%)
POLY-3 RATE (b)	0/41.78	0/38.07	0/36.67	0/37.91	2/35.44	0/36.44
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	5.6%	0.0%
TERMINAL (d)	0/25 (0%)	0/22 (0%)	0/24 (0%)	0/25 (0%)	2/20 (10%)	0/23 (0%)
FIRST INCIDENCE	---	---	---	---	728 (T)	---
STATISTICAL TESTS						
LIFE TABLE	P=0.448	(e)	(e)	(e)	P=0.190	(e)
POLY 3	P=0.442	(e)	(e)	(e)	P=0.202	(e)
POLY 1.5	P=0.452	(e)	(e)	(e)	P=0.210	(e)
POLY 6	P=0.426	(e)	(e)	(e)	P=0.198	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.190	(e)
COCH-ARM / FISHERS	P=0.458	(e)	(e)	(e)	P=0.243	(e)
ORDER RESTRICTED	P=0.152	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Parathyroid Gland Adenoma						
TUMOR RATES						
OVERALL (a)	0/49 (0%)	2/51 (4%)	0/44 (0%)	0/51 (0%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/38.63	2/37.50	0/31.58	0/37.26	0/34.13	0/33.79
POLY-3 PERCENT (g)	0.0%	5.3%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	0/24 (0%)	1/21 (5%)	0/22 (0%)	0/25 (0%)	0/19 (0%)	0/23 (0%)
FIRST INCIDENCE	---	503	---	---	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.300N	P=0.218	(e)	(e)	(e)	(e)
POLY 3	P=0.299N	P=0.230	(e)	(e)	(e)	(e)
POLY 1.5	P=0.293N	P=0.237	(e)	(e)	(e)	(e)
POLY 6	P=0.306N	P=0.222	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.284N	P=0.254	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.287N	P=0.258	(e)	(e)	(e)	(e)
ORDER RESTRICTED	P=0.209N	(e)	(e)	(e)	(e)	(e)

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Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma						
TUMOR RATES						
OVERALL (a)	15/53 (28%)	21/53 (40%)	23/53 (43%)	23/53 (43%)	21/53 (40%)	16/53 (30%)
POLY-3 RATE (b)	15/43.22	21/40.29	23/40.24	23/41.13	21/40.54	16/39.31
POLY-3 PERCENT (g)	34.7%	52.1%	57.2%	55.9%	51.8%	40.7%
TERMINAL (d)	8/25 (32%)	12/22 (55%)	13/24 (54%)	16/25 (64%)	8/20 (40%)	8/23 (35%)
FIRST INCIDENCE	603	600	420	470	420	549
STATISTICAL TESTS						
LIFE TABLE	P=0.420N	P=0.070	P=0.046 *	P=0.052	P=0.061	P=0.332
POLY 3	P=0.344N	P=0.075	P=0.027 *	P=0.034 *	P=0.081	P=0.367
POLY 1.5	P=0.313N	P=0.100	P=0.034 *	P=0.050	P=0.090	P=0.411
POLY 6	P=0.360N	P=0.058	P=0.027 *	P=0.022 *	P=0.089	P=0.335
LOGISTIC REGRESSION	P=0.383N	P=0.057	P=0.022 *	P=0.024 *	P=0.064	P=0.317
COCH-ARM / FISHERS	P=0.255N	P=0.153	P=0.078	P=0.078	P=0.153	P=0.500
ORDER RESTRICTED	P=0.085	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma						
TUMOR RATES						
OVERALL (a)	15/53 (28%)	22/53 (42%)	23/53 (43%)	23/53 (43%)	21/53 (40%)	16/53 (30%)
POLY-3 RATE (b)	15/43.22	22/40.53	23/40.24	23/41.13	21/40.54	16/39.31
POLY-3 PERCENT (g)	34.7%	54.3%	57.2%	55.9%	51.8%	40.7%
TERMINAL (d)	8/25 (32%)	12/22 (55%)	13/24 (54%)	16/25 (64%)	8/20 (40%)	8/23 (35%)
FIRST INCIDENCE	603	600	420	470	420	549
STATISTICAL TESTS						
LIFE TABLE	P=0.390N	P=0.049 *	P=0.046 *	P=0.052	P=0.061	P=0.332
POLY 3	P=0.311N	P=0.050	P=0.027 *	P=0.034 *	P=0.081	P=0.367
POLY 1.5	P=0.281N	P=0.068	P=0.034 *	P=0.050	P=0.090	P=0.411
POLY 6	P=0.329N	P=0.038 *	P=0.027 *	P=0.022 *	P=0.089	P=0.335
LOGISTIC REGRESSION	P=0.348N	P=0.037 *	P=0.022 *	P=0.024 *	P=0.064	P=0.317
COCH-ARM / FISHERS	P=0.227N	P=0.111	P=0.078	P=0.078	P=0.153	P=0.500
ORDER RESTRICTED	P=0.077	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Skin Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	1/53 (2%)	2/53 (4%)	1/53 (2%)	0/53 (0%)	2/53 (4%)
POLY-3 RATE (b)	0/41.78	1/38.37	2/36.87	1/38.22	0/36.13	2/37.38
POLY-3 PERCENT (g)	0.0%	2.6%	5.4%	2.6%	0.0%	5.4%
TERMINAL (d)	0/25 (0%)	0/22 (0%)	1/24 (4%)	1/25 (4%)	0/20 (0%)	1/23 (4%)
FIRST INCIDENCE	---	647	675	728 (T)	---	442
STATISTICAL TESTS						
LIFE TABLE	P=0.305	P=0.473	P=0.215	P=0.500	(e)	P=0.228
POLY 3	P=0.296	P=0.483	P=0.210	P=0.482	(e)	P=0.213
POLY 1.5	P=0.306	P=0.490	P=0.216	P=0.491	(e)	P=0.221
POLY 6	P=0.288	P=0.476	P=0.206	P=0.473	(e)	P=0.205
LOGISTIC REGRESSION	P=0.317	P=0.498	P=0.206	P=0.500	(e)	P=0.259
COCH-ARM / FISHERS	P=0.330	P=0.500	P=0.248	P=0.500	(e)	P=0.248
ORDER RESTRICTED	P=0.105	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Skin Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	2/53 (4%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	0/41.78	2/38.22	0/36.67	0/38.22	0/36.13	0/36.61
POLY-3 PERCENT (g)	0.0%	5.2%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	0/25 (0%)	1/22 (5%)	0/24 (0%)	0/25 (0%)	0/20 (0%)	0/23 (0%)
FIRST INCIDENCE	---	689	---	---	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.299N	P=0.211	(e)	(e)	(e)	(e)
POLY 3	P=0.304N	P=0.217	(e)	(e)	(e)	(e)
POLY 1.5	P=0.297N	P=0.225	(e)	(e)	(e)	(e)
POLY 6	P=0.309N	P=0.209	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.303N	P=0.206	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.288N	P=0.248	(e)	(e)	(e)	(e)
ORDER RESTRICTED	P=0.197N	(e)	(e)	(e)	(e)	(e)

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Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Thyroid Gland: C-Cell Adenoma						
TUMOR RATES						
OVERALL (a)	13/53 (25%)	10/53 (19%)	9/51 (18%)	9/53 (17%)	6/51 (12%)	7/51 (14%)
POLY-3 RATE (b)	13/43.49	10/39.80	9/36.75	9/38.42	6/35.57	7/36.03
POLY-3 PERCENT (g)	29.9%	25.1%	24.5%	23.4%	16.9%	19.4%
TERMINAL (d)	8/25 (32%)	5/22 (23%)	6/24 (25%)	8/25 (32%)	4/20 (20%)	5/23 (22%)
FIRST INCIDENCE	500	530	570	675	642	570
STATISTICAL TESTS						
LIFE TABLE	P=0.137N	P=0.475N	P=0.316N	P=0.269N	P=0.152N	P=0.178N
POLY 3	P=0.149N	P=0.404N	P=0.386N	P=0.340N	P=0.138N	P=0.207N
POLY 1.5	P=0.133N	P=0.370N	P=0.359N	P=0.288N	P=0.116N	P=0.174N
POLY 6	P=0.163N	P=0.437N	P=0.398N	P=0.406N	P=0.152N	P=0.238N
LOGISTIC REGRESSION	P=0.154N	P=0.392N	P=0.369N	P=0.342N	P=0.126N	P=0.197N
COCH-ARM / FISHERS	P=0.108N	P=0.319N	P=0.269N	P=0.237N	P=0.076N	P=0.125N
ORDER RESTRICTED	P=0.179N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Thyroid Gland: C-Cell Carcinoma						
TUMOR RATES						
OVERALL (a)	2/53 (4%)	2/53 (4%)	2/51 (4%)	2/53 (4%)	0/51 (0%)	1/51 (2%)
POLY-3 RATE (b)	2/41.78	2/38.36	2/36.00	2/38.22	0/35.23	1/35.09
POLY-3 PERCENT (g)	4.8%	5.2%	5.6%	5.2%	0.0%	2.9%
TERMINAL (d)	2/25 (8%)	1/22 (5%)	1/24 (4%)	2/25 (8%)	0/20 (0%)	1/23 (4%)
FIRST INCIDENCE	728 (T)	651	636	728 (T)	---	728 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.263N	P=0.644	P=0.665	P=0.697	P=0.288N	P=0.529N
POLY 3	P=0.271N	P=0.664	P=0.640	P=0.662	P=0.276N	P=0.561N
POLY 1.5	P=0.263N	P=0.675	P=0.647	P=0.677	P=0.268N	P=0.544N
POLY 6	P=0.276N	P=0.652	P=0.638	P=0.645	P=0.281N	P=0.575N
LOGISTIC REGRESSION	P=0.274N	P=0.644	P=0.634	P=0.697	(e)	P=0.529N
COCH-ARM / FISHERS	P=0.245N	P=0.691N	P=0.676	P=0.691N	P=0.257N	P=0.515N
ORDER RESTRICTED	P=0.363N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Thyroid Gland: C-Cell Carcinoma or Adenoma						
TUMOR RATES						
OVERALL (a)	15/53 (28%)	12/53 (23%)	10/51 (20%)	10/53 (19%)	6/51 (12%)	7/51 (14%)
POLY-3 RATE (b)	15/43.49	12/40.09	10/36.75	10/38.42	6/35.57	7/36.03
POLY-3 PERCENT (g)	34.5%	29.9%	27.2%	26.0%	16.9%	19.4%
TERMINAL (d)	10/25 (40%)	6/22 (27%)	7/24 (29%)	9/25 (36%)	4/20 (20%)	5/23 (22%)
FIRST INCIDENCE	500	530	570	675	642	570
STATISTICAL TESTS						
LIFE TABLE	P=0.052N	P=0.500N	P=0.249N	P=0.201N	P=0.075N	P=0.087N
POLY 3	P=0.055N	P=0.415N	P=0.322N	P=0.275N	P=0.063N	P=0.104N
POLY 1.5	P=0.048N*	P=0.381N	P=0.295N	P=0.226N	P=0.051N	P=0.083N
POLY 6	P=0.062N	P=0.445N	P=0.332N	P=0.341N	P=0.070N	P=0.123N
LOGISTIC REGRESSION	P=0.059N	P=0.421N	P=0.313N	P=0.287N	P=0.059N	P=0.105N
COCH-ARM / FISHERS	P=0.038N*	P=0.328N	P=0.210N	P=0.180N	P=0.031N*	P=0.056N
ORDER RESTRICTED	P=0.069N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Uterus Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	2/53 (4%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	2/41.97	0/38.07	0/36.67	0/38.22	0/36.13	0/36.61
POLY-3 PERCENT (g)	4.8%	0.0%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	1/25 (4%)	0/22 (0%)	0/24 (0%)	0/25 (0%)	0/20 (0%)	0/23 (0%)
FIRST INCIDENCE	678	---	---	---	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.262N	P=0.280N	P=0.274N	P=0.269N	P=0.295N	P=0.275N
POLY 3	P=0.225N	P=0.259N	P=0.268N	P=0.258N	P=0.272N	P=0.268N
POLY 1.5	P=0.234N	P=0.250N	P=0.260N	P=0.248N	P=0.262N	P=0.257N
POLY 6	P=0.215N	P=0.270N	P=0.275N	P=0.270N	P=0.278N	P=0.280N
LOGISTIC REGRESSION	P=0.261N	P=0.265N	P=0.270N	P=0.265N	P=0.273N	P=0.274N
COCH-ARM / FISHERS	P=0.248N	P=0.248N	P=0.248N	P=0.248N	P=0.248N	P=0.248N
ORDER RESTRICTED	P=0.013N*	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Uterus Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	1/53 (2%)	0/53 (0%)	1/53 (2%)	5/53 (9%)	2/53 (4%)
POLY-3 RATE (b)	1/41.97	1/38.16	0/36.67	1/38.22	5/36.27	2/36.98
POLY-3 PERCENT (g)	2.4%	2.6%	0.0%	2.6%	13.8%	5.4%
TERMINAL (d)	0/25 (0%)	0/22 (0%)	0/24 (0%)	1/25 (4%)	2/20 (10%)	1/23 (4%)
FIRST INCIDENCE	678	706	---	728 (T)	707	624
STATISTICAL TESTS						
LIFE TABLE	P=0.107	P=0.713	P=0.554N	P=0.731	P=0.071	P=0.438
POLY 3	P=0.103	P=0.740	P=0.527N	P=0.740	P=0.070	P=0.456
POLY 1.5	P=0.110	P=0.748	P=0.520N	P=0.750	P=0.078	P=0.472
POLY 6	P=0.096	P=0.730	P=0.532N	P=0.728	P=0.065	P=0.441
LOGISTIC REGRESSION	P=0.097	P=0.741	P=0.521N	P=0.735	P=0.067	P=0.464
COCH-ARM / FISHERS	P=0.121	P=0.752N	P=0.500N	P=0.752N	P=0.103	P=0.500
ORDER RESTRICTED	P=0.062	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	Females 44 NG/KG	92 NG/KG	200 NG/KG
Uterus Polyp Stromal						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	9/53 (17%)	3/53 (6%)	6/53 (11%)	5/53 (9%)	7/53 (13%)	4/53 (8%)
POLY-3 RATE (b)	9/43.07	3/38.73	6/36.87	5/38.22	7/36.66	4/37.55
POLY-3 PERCENT (g)	20.9%	7.8%	16.3%	13.1%	19.1%	10.7%
TERMINAL (d)	4/25 (16%)	1/22 (5%)	5/24 (21%)	5/25 (20%)	3/20 (15%)	2/23 (9%)
FIRST INCIDENCE	588	547	675	728 (T)	667	498
STATISTICAL TESTS						
LIFE TABLE	P=0.370N	P=0.118N	P=0.376N	P=0.243N	P=0.561N	P=0.196N
POLY 3	P=0.343N	P=0.084N	P=0.405N	P=0.261N	P=0.532N	P=0.172N
POLY 1.5	P=0.329N	P=0.073N	P=0.370N	P=0.227N	P=0.491N	P=0.149N
POLY 6	P=0.354N	P=0.099N	P=0.441N	P=0.311N	P=0.561N	P=0.198N
LOGISTIC REGRESSION	P=0.374N	P=0.079N	P=0.395N	P=0.267N	P=0.522N	P=0.158N
COCH-ARM / FISHERS	P=0.305N	P=0.061N	P=0.289N	P=0.195N	P=0.393N	P=0.118N
ORDER RESTRICTED	P=0.155N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
Uterus						
Sarcoma Stromal or Polyp Stromal						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	9/53 (17%)	4/53 (8%)	6/53 (11%)	5/53 (9%)	7/53 (13%)	4/53 (8%)
POLY-3 RATE (b)	9/43.07	4/39.40	6/36.87	5/38.22	7/36.66	4/37.55
POLY-3 PERCENT (g)	20.9%	10.2%	16.3%	13.1%	19.1%	10.7%
TERMINAL (d)	4/25 (16%)	1/22 (5%)	5/24 (21%)	5/25 (20%)	3/20 (15%)	2/23 (9%)
FIRST INCIDENCE	588	503	675	728 (T)	667	498
STATISTICAL TESTS						
LIFE TABLE	P=0.323N	P=0.199N	P=0.376N	P=0.243N	P=0.561N	P=0.196N
POLY 3	P=0.303N	P=0.149N	P=0.405N	P=0.261N	P=0.532N	P=0.172N
POLY 1.5	P=0.286N	P=0.135N	P=0.370N	P=0.227N	P=0.491N	P=0.149N
POLY 6	P=0.317N	P=0.168N	P=0.441N	P=0.311N	P=0.561N	P=0.198N
LOGISTIC REGRESSION	P=0.320N	P=0.135N	P=0.395N	P=0.267N	P=0.522N	P=0.158N
COCH-ARM / FISHERS	P=0.260N	P=0.118N	P=0.289N	P=0.195N	P=0.393N	P=0.118N
ORDER RESTRICTED	P=0.161N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
All Organs						
Benign Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	45/53 (85%)	45/53 (85%)	43/53 (81%)	42/53 (79%)	45/53 (85%)	41/53 (77%)
POLY-3 RATE (b)	45/50.55	45/48.80	43/45.62	42/47.71	45/46.75	41/46.25
POLY-3 PERCENT (g)	89.0%	92.2%	94.3%	88.0%	96.3%	88.6%
TERMINAL (d)	21/25 (84%)	20/22 (91%)	22/24 (92%)	22/25 (88%)	19/20 (95%)	20/23 (87%)
FIRST INCIDENCE	289	289	393	302	321	326
STATISTICAL TESTS						
LIFE TABLE	P=0.473	P=0.245	P=0.409	P=0.543	P=0.152	P=0.467
POLY 3	P=0.472N	P=0.414	P=0.278	P=0.571N	P=0.146	P=0.613N
POLY 1.5	P=0.344N	P=0.497	P=0.371	P=0.431N	P=0.229	P=0.457N
POLY 6	P=0.552	P=0.345	P=0.279	P=0.564	P=0.131	P=0.545
LOGISTIC REGRESSION	P=0.342N	P=0.513	P=0.455	P=0.366N	P=0.265	P=0.391N
COCH-ARM / FISHERS	P=0.215N	P=0.607N	P=0.398N	P=0.307N	P=0.607N	P=0.229N
ORDER RESTRICTED	P=0.450	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
All Organs Malignant Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	12/53 (23%)	20/53 (38%)	21/53 (40%)	13/53 (25%)	16/53 (30%)	16/53 (30%)
POLY-3 RATE (b)	12/43.55	20/42.49	21/43.07	13/41.30	16/40.31	16/43.29
POLY-3 PERCENT (g)	27.6%	47.1%	48.8%	31.5%	39.7%	37.0%
TERMINAL (d)	7/25 (28%)	8/22 (36%)	10/24 (42%)	8/25 (32%)	6/20 (30%)	5/23 (22%)
FIRST INCIDENCE	377	420	196	302	113	329
STATISTICAL TESTS						
LIFE TABLE	P=0.505	P=0.041 *	P=0.036 *	P=0.445	P=0.136	P=0.178
POLY 3	P=0.454N	P=0.044 *	P=0.030 *	P=0.437	P=0.168	P=0.236
POLY 1.5	P=0.460N	P=0.051	P=0.033 *	P=0.471	P=0.192	P=0.238
POLY 6	P=0.434N	P=0.041 *	P=0.030 *	P=0.396	P=0.154	P=0.244
LOGISTIC REGRESSION	P=0.450N	P=0.050	P=0.046 *	P=0.473	P=0.227	P=0.281
COCH-ARM / FISHERS	P=0.448N	P=0.069	P=0.046 *	P=0.500	P=0.255	P=0.255
ORDER RESTRICTED	P=0.155	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
			Females			
All Organs Malignant and Benign Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	48/53 (91%)	49/53 (92%)	49/53 (92%)	44/53 (83%)	48/53 (91%)	46/53 (87%)
POLY-3 RATE (b)	48/51.69	49/50.68	49/49.46	44/49.02	48/49.59	46/49.29
POLY-3 PERCENT (g)	92.9%	96.7%	99.1%	89.8%	96.8%	93.3%
TERMINAL (d)	22/25 (88%)	21/22 (96%)	24/24 (100%)	22/25 (88%)	19/20 (95%)	21/23 (91%)
FIRST INCIDENCE	289	289	196	302	113	326
STATISTICAL TESTS						
LIFE TABLE	P=0.408	P=0.200	P=0.250	P=0.521N	P=0.152	P=0.348
POLY 3	P=0.415N	P=0.325	P=0.121	P=0.414N	P=0.317	P=0.626
POLY 1.5	P=0.352N	P=0.386	P=0.183	P=0.291N	P=0.406	P=0.601N
POLY 6	P=0.492N	P=0.287	P=0.103	P=0.566N	P=0.283	P=0.550
LOGISTIC REGRESSION	P=0.342N	P=0.430	P=0.255	P=0.224N	P=0.452	P=0.512N
COCH-ARM / FISHERS	P=0.253N	P=0.500	P=0.500	P=0.195N	P=0.629N	P=0.380N
ORDER RESTRICTED	P=0.422N	(e)	(e)	(e)	(e)	(e)

(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).

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION(PECDF)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

FINAL #2 RATS CONTROL VS STOP

REASONS FOR REMOVAL:
25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:
INCLUDE 001 0 NG/KG
INCLUDE 007 200 NG/ KG STOP

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 05
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD
Rats(SPRAGUE-DAWLEY)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION(PECDF)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/23/03
TIME: 10:55:07

NTP C#: 96007F
CAS: 57117-31-4

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
Kidney
Liver
Ovary
Pancreas
Pituitary Gland
Thyroid Gland

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 05
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION(PECDF)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/23/03
TIME: 10:55:07

NTP C#: 96007F
CAS: 57117-31-4

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TOXIC EQUIVALENCY FACTOR EVALUATION(

Female Rats

Organ	Morphology
Adrenal Medulla	Pheochromocytoma Benign
	Pheochromocytoma: Benign, Complex, Malignant, NOS
Mammary Gland	Adenoma
	Carcinoma
	Carcinoma or Adenoma
	Fibroadenoma
	Fibroma, Fibroadenoma or Adenoma
	Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)	Squamous Cell Carcinoma
	Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma
Oral Mucosa	Squamous Cell Carcinoma
Pancreas	Carcinoma or Adenoma
Pituitary Gland: Pars Distalis or Unspecified Site	Adenoma
Skin	Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma
	Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma
Thyroid Gland: C-Cell	Adenoma
	Carcinoma
	Carcinoma or Adenoma
Uterus	Adenoma
	Polyp Stromal
All Organs	Benign Tumors
	Malignant Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Adrenal Medulla		
Pheochromocytoma Benign		
TUMOR RATES		
OVERALL (a)	4/53 (8%)	1/48 (2%)
POLY-3 RATE (b)	4/42.04	1/32.61
POLY-3 PERCENT (g)	9.5%	3.1%
TERMINAL (d)	3/25 (12%)	1/15 (7%)
FIRST INCIDENCE	659	728 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.348N
POLY 3		P=0.286N
POLY 1.5		P=0.256N
POLY 6		P=0.325N
LOGISTIC REGRESSION		P=0.300N
COCH-ARM / FISHERS		P=0.214N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Adrenal Medulla		
Pheochromocytoma: Benign, Complex, Malignant, NOS		
TUMOR RATES		
OVERALL (a)	5/53 (9%)	1/48 (2%)
POLY-3 RATE (b)	5/42.04	1/32.61
POLY-3 PERCENT (g)	11.9%	3.1%
TERMINAL (d)	4/25 (16%)	1/15 (7%)
FIRST INCIDENCE	659	728 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.245N
POLY 3		P=0.186N
POLY 1.5		P=0.161N
POLY 6		P=0.218N
LOGISTIC REGRESSION		P=0.203N
COCH-ARM / FISHERS		P=0.127N
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Mammary Gland Adenoma		
TUMOR RATES	#	#
OVERALL (a)	1/53 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/41.78	2/33.36
POLY-3 PERCENT (g)	2.4%	6.0%
TERMINAL (d)	1/25 (4%)	1/15 (7%)
FIRST INCIDENCE	728 (T)	610
STATISTICAL TESTS		
LIFE TABLE		P=0.352
POLY 3		P=0.453
POLY 1.5		P=0.464
POLY 6		P=0.442
LOGISTIC REGRESSION		P=0.411
COCH-ARM / FISHERS		P=0.478
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Mammary Gland Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	5/53 (9%)	5/50 (10%)
POLY-3 RATE (b)	5/42.44	5/33.62
POLY-3 PERCENT (g)	11.8%	14.9%
TERMINAL (d)	3/25 (12%)	4/15 (27%)
FIRST INCIDENCE	619	500
STATISTICAL TESTS		
LIFE TABLE		P=0.339
POLY 3		P=0.497
POLY 1.5		P=0.535
POLY 6		P=0.454
LOGISTIC REGRESSION		P=0.471
COCH-ARM / FISHERS		P=0.592
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Mammary Gland Carcinoma or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	6/53 (11%)	7/50 (14%)
POLY-3 RATE (b)	6/42.44	7/34.03
POLY-3 PERCENT (g)	14.1%	20.6%
TERMINAL (d)	4/25 (16%)	5/15 (33%)
FIRST INCIDENCE	619	500
STATISTICAL TESTS		
LIFE TABLE		P=0.191
POLY 3		P=0.346
POLY 1.5		P=0.387
POLY 6		P=0.303
LOGISTIC REGRESSION		P=0.314
COCH-ARM / FISHERS		P=0.455
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Mammary Gland Fibroadenoma		
TUMOR RATES	#	#
OVERALL (a)	34/53 (64%)	34/50 (68%)
POLY-3 RATE (b)	34/49.74	34/42.97
POLY-3 PERCENT (g)	68.4%	79.1%
TERMINAL (d)	14/25 (56%)	9/15 (60%)
FIRST INCIDENCE	289	276
STATISTICAL TESTS		
LIFE TABLE		P=0.057
POLY 3		P=0.171
POLY 1.5		P=0.238
POLY 6		P=0.132
LOGISTIC REGRESSION		P=0.353
COCH-ARM / FISHERS		P=0.419
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Mammary Gland Fibroma, Fibroadenoma or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	35/53 (66%)	34/50 (68%)
POLY-3 RATE (b)	35/49.74	34/42.97
POLY-3 PERCENT (g)	70.4%	79.1%
TERMINAL (d)	15/25 (60%)	9/15 (60%)
FIRST INCIDENCE	289	276
STATISTICAL TESTS		
LIFE TABLE		P=0.069
POLY 3		P=0.232
POLY 1.5		P=0.309
POLY 6		P=0.186
LOGISTIC REGRESSION		P=0.420
COCH-ARM / FISHERS		P=0.499
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	38/53 (72%)	36/50 (72%)
POLY-3 RATE (b)	38/50.41	36/42.97
POLY-3 PERCENT (g)	75.4%	83.8%
TERMINAL (d)	16/25 (64%)	11/15 (73%)
FIRST INCIDENCE	289	276
STATISTICAL TESTS		
LIFE TABLE		P=0.069
POLY 3		P=0.227
POLY 1.5		P=0.335
POLY 6		P=0.153
LOGISTIC REGRESSION		P=0.454
COCH-ARM / FISHERS		P=0.574
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	1/53 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/41.78	3/33.25
POLY-3 PERCENT (g)	2.4%	9.0%
TERMINAL (d)	1/25 (4%)	1/15 (7%)
FIRST INCIDENCE	728 (T)	680
STATISTICAL TESTS		
LIFE TABLE		P=0.179
POLY 3		P=0.249
POLY 1.5		P=0.263
POLY 6		P=0.236
LOGISTIC REGRESSION		P=0.192
COCH-ARM / FISHERS		P=0.287
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma		
TUMOR RATES	#	#
OVERALL (a)	1/53 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/41.78	3/33.25
POLY-3 PERCENT (g)	2.4%	9.0%
TERMINAL (d)	1/25 (4%)	1/15 (7%)
FIRST INCIDENCE	728 (T)	680
STATISTICAL TESTS		
LIFE TABLE		P=0.179
POLY 3		P=0.249
POLY 1.5		P=0.263
POLY 6		P=0.236
LOGISTIC REGRESSION		P=0.192
COCH-ARM / FISHERS		P=0.287
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Oral Mucosa		
Squamous Cell Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	1/53 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/41.78	3/33.25
POLY-3 PERCENT (g)	2.4%	9.0%
TERMINAL (d)	1/25 (4%)	1/15 (7%)
FIRST INCIDENCE	728 (T)	680
STATISTICAL TESTS		
LIFE TABLE		P=0.179
POLY 3		P=0.249
POLY 1.5		P=0.263
POLY 6		P=0.236
LOGISTIC REGRESSION		P=0.192
COCH-ARM / FISHERS		P=0.287
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Pancreas		
Carcinoma or Adenoma		
TUMOR RATES		
OVERALL (a)	0/53 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/41.78	2/32.92
POLY-3 PERCENT (g)	0.0%	6.1%
TERMINAL (d)	0/25 (0%)	2/15 (13%)
FIRST INCIDENCE	---	728 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.134
POLY 3		P=0.215
POLY 1.5		P=0.220
POLY 6		P=0.212
LOGISTIC REGRESSION		P=0.134
COCH-ARM / FISHERS		P=0.228
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	 200 NG/ KG STOP
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma		
TUMOR RATES		
OVERALL (a)	15/53 (28%)	13/49 (27%)
POLY-3 RATE (b)	15/43.22	13/34.20
POLY-3 PERCENT (g)	34.7%	38.0%
TERMINAL (d)	8/25 (32%)	5/15 (33%)
FIRST INCIDENCE	603	610
STATISTICAL TESTS		
LIFE TABLE		P=0.267
POLY 3		P=0.488
POLY 1.5		P=0.557
POLY 6		P=0.421
LOGISTIC REGRESSION		P=0.397
COCH-ARM / FISHERS		P=0.509N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	 200 NG/ KG STOP
Skin Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma		
TUMOR RATES	#	#
OVERALL (a)	0/53 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/41.78	3/34.88
POLY-3 PERCENT (g)	0.0%	8.6%
TERMINAL (d)	0/25 (0%)	0/15 (0%)
FIRST INCIDENCE	---	240
STATISTICAL TESTS		
LIFE TABLE		P=0.100
POLY 3		P=0.099
POLY 1.5		P=0.104
POLY 6		P=0.094
LOGISTIC REGRESSION		P=0.188
COCH-ARM / FISHERS		P=0.111
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Skin		
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma		
TUMOR RATES	#	#
OVERALL (a)	0/53 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/41.78	2/34.73
POLY-3 PERCENT (g)	0.0%	5.8%
TERMINAL (d)	0/25 (0%)	0/15 (0%)
FIRST INCIDENCE	---	240
STATISTICAL TESTS		
LIFE TABLE		P=0.222
POLY 3		P=0.219
POLY 1.5		P=0.223
POLY 6		P=0.215
LOGISTIC REGRESSION		P=0.390
COCH-ARM / FISHERS		P=0.233
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Thyroid Gland: C-Cell		
Adenoma		
TUMOR RATES		
OVERALL (a)	13/53 (25%)	5/48 (10%)
POLY-3 RATE (b)	13/43.49	5/33.34
POLY-3 PERCENT (g)	29.9%	15.0%
TERMINAL (d)	8/25 (32%)	3/15 (20%)
FIRST INCIDENCE	500	525
STATISTICAL TESTS		
LIFE TABLE		P=0.211N
POLY 3		P=0.111N
POLY 1.5		P=0.084N
POLY 6		P=0.149N
LOGISTIC REGRESSION		P=0.097N
COCH-ARM / FISHERS		P=0.055N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	 200 NG/ KG STOP
Thyroid Gland: C-Cell Carcinoma		
TUMOR RATES		
OVERALL (a)	2/53 (4%)	0/48 (0%)
POLY-3 RATE (b)	2/41.78	0/32.61
POLY-3 PERCENT (g)	4.8%	0.0%
TERMINAL (d)	2/25 (8%)	0/15 (0%)
FIRST INCIDENCE	728 (T)	---
STATISTICAL TESTS		
LIFE TABLE		P=0.356N
POLY 3		P=0.331N
POLY 1.5		P=0.306N
POLY 6		P=0.363N
LOGISTIC REGRESSION		(e)
COCH-ARM / FISHERS		P=0.273N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	 200 NG/ KG STOP
Thyroid Gland: C-Cell Carcinoma or Adenoma		
TUMOR RATES		
OVERALL (a)	15/53 (28%)	5/48 (10%)
POLY-3 RATE (b)	15/43.49	5/33.34
POLY-3 PERCENT (g)	34.5%	15.0%
TERMINAL (d)	10/25 (40%)	3/15 (20%)
FIRST INCIDENCE	500	525
STATISTICAL TESTS		
LIFE TABLE		P=0.121N
POLY 3		P=0.049N*
POLY 1.5		P=0.035N*
POLY 6		P=0.070N
LOGISTIC REGRESSION		P=0.047N*
COCH-ARM / FISHERS		P=0.021N*
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Uterus Adenoma		
TUMOR RATES	#	#
OVERALL (a)	2/53 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/41.97	0/32.95
POLY-3 PERCENT (g)	4.8%	0.0%
TERMINAL (d)	1/25 (4%)	0/15 (0%)
FIRST INCIDENCE	678	---
STATISTICAL TESTS		
LIFE TABLE		P=0.338N
POLY 3		P=0.331N
POLY 1.5		P=0.300N
POLY 6		P=0.368N
LOGISTIC REGRESSION		P=0.307N
COCH-ARM / FISHERS		P=0.262N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
Uterus Polyp Stromal		
TUMOR RATES	#	#
OVERALL (a)	9/53 (17%)	4/50 (8%)
POLY-3 RATE (b)	9/43.07	4/34.77
POLY-3 PERCENT (g)	20.9%	11.5%
TERMINAL (d)	4/25 (16%)	1/15 (7%)
FIRST INCIDENCE	588	451
STATISTICAL TESTS		
LIFE TABLE		P=0.324N
POLY 3		P=0.224N
POLY 1.5		P=0.189N
POLY 6		P=0.268N
LOGISTIC REGRESSION		P=0.168N
COCH-ARM / FISHERS		P=0.141N
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
All Organs Benign Tumors		
TUMOR RATES	#	#
OVERALL (a)	45/53 (85%)	40/50 (80%)
POLY-3 RATE (b)	45/50.55	40/43.88
POLY-3 PERCENT (g)	89.0%	91.2%
TERMINAL (d)	21/25 (84%)	13/15 (87%)
FIRST INCIDENCE	289	276
STATISTICAL TESTS		
LIFE TABLE		P=0.080
POLY 3		P=0.511
POLY 1.5		P=0.640
POLY 6		P=0.409
LOGISTIC REGRESSION		P=0.587N
COCH-ARM / FISHERS		P=0.346N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 200 NG/KG STOP
All Organs Malignant Tumors		
TUMOR RATES	#	#
OVERALL (a)	12/53 (23%)	13/50 (26%)
POLY-3 RATE (b)	12/43.55	13/36.43
POLY-3 PERCENT (g)	27.6%	35.7%
TERMINAL (d)	7/25 (28%)	5/15 (33%)
FIRST INCIDENCE	377	240
STATISTICAL TESTS		
LIFE TABLE		P=0.145
POLY 3		P=0.301
POLY 1.5		P=0.353
POLY 6		P=0.249
LOGISTIC REGRESSION		P=0.364
COCH-ARM / FISHERS		P=0.433
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION(
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	200 NG/KG STOP
All Organs Malignant and Benign Tumors		
TUMOR RATES	#	#
OVERALL (a)	48/53 (91%)	43/50 (86%)
POLY-3 RATE (b)	48/51.69	43/45.66
POLY-3 PERCENT (g)	92.9%	94.2%
TERMINAL (d)	22/25 (88%)	14/15 (93%)
FIRST INCIDENCE	289	240
STATISTICAL TESTS		
LIFE TABLE		P=0.069
POLY 3		P=0.577
POLY 1.5		P=0.619N
POLY 6		P=0.437
LOGISTIC REGRESSION		P=0.509N
COCH-ARM / FISHERS		P=0.339N
ORDER RESTRICTED		(e)

(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]
TOXIC EQUIVALENCY FACTOR EVALUATION(PECDF)

FINAL #2 RATS

Facility: Battelle Columbus Laboratory

Chemical CAS #: 57117-31-4

Lock Date: 07/25/02

Cage Range: All

Reasons For Removal: 25018 Dosing Accident; 25019 Moribund Sacrifice; 25020 Natural Death; 25021 Terminal Sacrifice

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]
TOXIC EQUIVALENCY FACTOR EVALUATION(PECDF)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
DISPOSITION SUMMARY						
Animals Initially In Study	98	98	98	98	98	98
Early Deaths						
Natural Death	7	10	10	8	14	11
Moribund Sacrifice	21	20	17	19	19	19
Dosing Accident		1	2	1		
Survivors						
Terminal Sacrifice	25	22	24	25	20	23
Animals Examined Microscopically	53	53	53	53	53	53
ALIMENTARY SYSTEM						
Esophagus	(53)	(53)	(52)	(53)	(53)	(53)
Cyst				2 [3.0]		
Perforation		1 [0.0]	2 [3.0]	1 [4.0]		
Muscularis, Inflammation		2 [1.5]	1 [1.0]	1 [1.0]	1 [2.0]	1 [2.0]
Periesophageal Tissue, Inflammation		1 [3.0]	2 [3.0]	2 [3.0]	1 [3.0]	
Intestine Large, Colon	(53)	(53)	(53)	(53)	(51)	(53)
Edema					1 [2.0]	
Inflammation					1 [2.0]	1 [2.0]
Parasite Metazoan	2					
Intestine Large, Rectum	(53)	(53)	(53)	(53)	(52)	(53)
Parasite Metazoan	4	5	5	1	1	1
Artery, Inflammation, Chronic Active		1 [3.0]		1 [3.0]		
Intestine Large, Cecum	(53)	(53)	(53)	(52)	(51)	(53)
Inflammation					1 [2.0]	
Artery, Inflammation, Chronic Active		1 [3.0]				2 [2.5]
Artery, Mineralization					1 [2.0]	
Intestine Small, Ileum	(53)	(53)	(53)	(52)	(52)	(53)
Parasite Metazoan	1					
Liver	(53)	(53)	(53)	(52)	(53)	(53)
Angiectasis	6 [1.5]	3 [1.3]	4 [1.8]	1 [2.0]		1 [2.0]
Basophilic Focus	10	11	9	10	12	6
Basophilic Focus, Multiple	12	12	11	6	3	1
Cholangiofibrosis		1 [1.0]		3 [1.3]	3 [1.3]	5 [2.2]
Clear Cell Focus	11	1	7	2		3
Clear Cell Focus, Multiple	2	5	3	1	6	8
Degeneration, Cystic						1 [1.0]
Eosinophilic Focus	7	11	9	9	11	10
Eosinophilic Focus, Multiple	8	2	9	9	12	18
Fatty Change, Diffuse	1 [1.0]	4 [1.3]	10 [1.4]	12 [1.1]	20 [1.1]	26 [1.3]

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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
ALIMENTARY SYSTEM - CONT						
Fatty Change, Focal	5 [1.2]	6 [2.0]	5 [1.0]	6 [1.3]	6 [1.3]	4 [1.0]
Hematopoietic Cell Proliferation	24 [1.1]	28 [1.3]	27 [1.1]	24 [1.0]	39 [1.1]	31 [1.1]
Hemorrhage	1 [2.0]					
Hepatodiaphragmatic Nodule	3	3	3	1	1	1
Hyperplasia, Nodular				3	8	12
Inflammation	47 [1.1]	44 [1.2]	47 [1.1]	50 [1.2]	48 [1.2]	50 [1.3]
Mixed Cell Focus	5		1	2	2	1
Mixed Cell Focus, Multiple	28	24	23	27	25	25
Necrosis	4 [2.5]	10 [2.1]	3 [2.0]	3 [2.3]	6 [2.0]	18 [1.8]
Pigmentation	13 [1.1]	11 [1.1]	21 [1.3]	44 [1.5]	42 [1.8]	48 [1.9]
Toxic Hepatopathy		2 [1.0]	3 [1.0]	8 [1.1]	27 [1.1]	44 [1.7]
Artery, Inflammation, Chronic Active						1 [1.0]
Bile Duct, Cyst	7 [2.3]	4 [2.3]	2 [3.0]	3 [2.0]	2 [2.0]	7 [1.7]
Bile Duct, Fibrosis	1 [1.0]	4 [1.8]	2 [1.0]	2 [1.5]	3 [1.0]	6 [1.3]
Bile Duct, Hyperplasia	3 [1.3]	2 [1.0]	2 [1.0]	2 [1.0]	1 [1.0]	13 [1.6]
Centrilobular, Degeneration	4 [2.0]	2 [1.5]	3 [2.3]	4 [1.5]	4 [2.3]	5 [2.4]
Hepatocyte, Hypertrophy	2 [1.0]	13 [1.0]	17 [1.0]	17 [1.0]	24 [1.0]	34 [1.2]
Hepatocyte, Multinucleated			4 [1.0]	13 [1.0]	18 [1.3]	35 [1.2]
Oval Cell, Hyperplasia	1 [1.0]	4 [1.3]	2 [1.0]	6 [1.2]	15 [1.1]	35 [1.4]
Portal, Fibrosis						1 [1.0]
Mesentery	(1)	(2)	(1)	(3)	(2)	(4)
Inflammation		1 [2.0]				
Necrosis			1 [3.0]			
Artery, Inflammation, Chronic Active		1 [3.0]		2 [3.5]	1 [4.0]	4 [3.3]
Fat, Necrosis	1 [3.0]			1 [2.0]	1 [3.0]	
Oral Mucosa	(52)	(53)	(52)	(53)	(53)	(53)
Gingival, Cyst				1 [3.0]		
Gingival, Hyperplasia				1 [1.0]		
Gingival, Hyperplasia, Squamous	15 [1.1]	11 [1.4]	16 [1.4]	19 [1.2]	22 [1.1]	20 [1.4]
Pancreas	(53)	(53)	(53)	(52)	(52)	(52)
Cyst					1 [2.0]	
Cytoplasmic Alteration						3 [2.0]
Inflammation, Chronic Active	2 [1.0]	1 [2.0]	1 [1.0]	1 [1.0]		4 [2.0]
Lipomatosis				1 [2.0]		
Acinus, Atrophy	3 [1.7]	1 [4.0]	1 [1.0]	1 [2.0]		3 [2.7]
Acinus, Hyperplasia		1 [3.0]				
Acinus, Vacuolization Cytoplasmic					2 [1.0]	23 [1.1]
Artery, Inflammation, Chronic Active	1 [1.0]	2 [2.0]	1 [1.0]	2 [2.5]	4 [2.3]	11 [3.3]
Duct, Dilatation						1 [4.0]
Salivary Glands	(53)	(53)	(51)	(53)	(51)	(51)
Atrophy	1 [2.0]					2 [1.5]
Duct, Inflammation		1 [3.0]				
Stomach, Forestomach	(53)	(53)	(53)	(53)	(52)	(53)

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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
ALIMENTARY SYSTEM - CONT						
Cyst						1 [3.0]
Edema		1 [2.0]				
Hyperkeratosis			1 [2.0]			
Hyperplasia, Squamous	4 [1.8]	1 [1.0]	5 [1.4]	6 [2.5]	3 [2.7]	10 [2.1]
Inflammation	1 [2.0]	1 [1.0]		2 [2.5]	2 [2.5]	2 [2.0]
Mineralization				1 [2.0]		
Ulcer		1 [1.0]	2 [1.5]	2 [2.0]	1 [3.0]	1 [2.0]
Artery, Inflammation, Chronic Active					1 [2.0]	3 [2.7]
Stomach, Glandular	(53)	(53)	(53)	(53)	(52)	(53)
Erosion			1 [2.0]	2 [2.0]	1 [2.0]	
Hyperplasia				1 [2.0]		
Inflammation	1 [2.0]			1 [2.0]		
Mineralization	2 [1.0]	9 [1.1]	1 [1.0]	3 [1.3]	2 [2.0]	4 [1.5]
Ulcer	1 [2.0]					
Artery, Inflammation, Chronic Active					1 [3.0]	1 [2.0]
Serosa, Inflammation		1 [2.0]				
Tooth	(33)	(25)	(22)	(30)	(29)	(29)
Peridontal Tissue, Inflammation	33 [1.6]	25 [1.4]	22 [1.1]	30 [1.6]	29 [1.1]	29 [1.3]
CARDIOVASCULAR SYSTEM						
Blood Vessel	(53)	(53)	(53)	(53)	(53)	(53)
Aorta, Mineralization		1 [3.0]		1 [3.0]	2 [2.5]	
Aorta, Adventitia, Inflammation, Chronic Active					1 [4.0]	
Heart	(53)	(53)	(52)	(53)	(53)	(52)
Cardiomyopathy	15 [1.1]	12 [1.0]	19 [1.1]	13 [1.0]	18 [1.0]	24 [1.1]
Hemorrhage	2 [2.0]					
Infiltration Cellular, Mononuclear Cell						1 [1.0]
Inflammation	1 [2.0]		1 [3.0]	1 [2.0]		
Mineralization				1 [2.0]	1 [2.0]	1 [2.0]
Artery, Inflammation, Chronic Active					1 [2.0]	2 [1.5]
Epicardium, Inflammation		1 [3.0]				1 [2.0]
ENDOCRINE SYSTEM						
Adrenal Cortex	(53)	(53)	(53)	(52)	(53)	(53)
Angiectasis	31 [1.5]	37 [1.4]	30 [1.4]	33 [1.4]	27 [1.2]	35 [1.3]
Atrophy	3 [3.3]			1 [4.0]		4 [2.3]
Degeneration, Cystic	4 [2.0]	17 [1.9]	14 [2.3]	18 [2.2]	12 [2.1]	14 [2.4]
Hematopoietic Cell Proliferation			1 [2.0]		1 [1.0]	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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
ENDOCRINE SYSTEM - CONT						
Hemorrhage	1 [4.0]			1 [3.0]		
Hyperplasia	8 [2.4]	10 [2.0]	10 [2.1]	7 [2.3]	10 [2.1]	11 [1.8]
Hypertrophy	42 [1.7]	43 [1.9]	43 [2.1]	46 [2.1]	44 [2.1]	45 [2.1]
Necrosis	4 [2.3]		2 [2.0]		2 [2.0]	
Vacuolization Cytoplasmic	9 [1.4]	13 [1.2]	14 [1.6]	7 [1.9]	17 [1.2]	9 [1.4]
Adrenal Medulla	(53)	(53)	(53)	(52)	(53)	(53)
Hyperplasia	11 [2.3]	12 [2.2]	14 [1.9]	14 [1.9]	7 [1.9]	10 [1.9]
Islets, Pancreatic	(53)	(53)	(53)	(52)	(52)	(52)
Hyperplasia						2 [2.5]
Parathyroid Gland	(49)	(51)	(44)	(51)	(49)	(49)
Hyperplasia		1 [2.0]	1 [2.0]		1 [2.0]	1 [2.0]
Hypertrophy		1 [2.0]				
Pituitary Gland	(53)	(53)	(53)	(53)	(53)	(53)
Angiectasis	20 [1.9]	21 [2.5]	20 [2.5]	13 [2.4]	12 [2.4]	14 [2.2]
Atrophy	1 [4.0]					
Cyst	2 [1.5]			1 [2.0]	1 [3.0]	1 [2.0]
Cytoplasmic Alteration	1 [1.0]				1 [1.0]	
Vacuolization Cytoplasmic	2 [1.0]	2 [1.0]	1 [1.0]			
Pars Distalis, Hyperplasia	22 [2.4]	16 [2.4]	14 [2.3]	11 [2.5]	15 [2.3]	19 [2.6]
Pars Intermedia, Hyperplasia	1 [2.0]					
Rathke's Cleft, Pars Intermedia, Hyperplasia					1 [2.0]	
Thyroid Gland	(53)	(53)	(51)	(53)	(51)	(51)
Inflammation			1 [3.0]			
C-Cell, Hyperplasia	15 [2.1]	16 [2.2]	9 [2.3]	13 [1.9]	9 [2.0]	11 [1.8]
Follicle, Cyst	1 [2.0]			1 [2.0]	1 [2.0]	
Follicular Cell, Hypertrophy	7 [1.6]	13 [1.2]	24 [1.3]	24 [1.2]	24 [1.5]	22 [1.5]
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(53)	(51)	(53)	(53)	(50)	(53)
Hyperplasia, Squamous			1 [2.0]			
Inflammation	52 [1.7]	47 [1.8]	46 [1.7]	51 [1.7]	47 [1.5]	47 [1.5]
Duct, Cyst	40 [2.3]	37 [2.3]	34 [2.6]	41 [2.4]	44 [2.0]	40 [2.2]
Ovary	(53)	(53)	(53)	(52)	(52)	(53)
Atrophy	43 [4.0]	40 [4.0]	38 [4.0]	43 [4.0]	45 [4.0]	45 [3.9]
Cyst	11 [2.2]	18 [2.1]	20 [2.1]	17 [2.3]	18 [2.3]	13 [2.5]
Fibrosis				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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
GENITAL SYSTEM - CONT						
Inflammation, Chronic Active	1 [4.0]				1 [3.0]	1 [4.0]
Oviduct	(1)				(1)	
Cyst	1 [3.0]					
Inflammation, Chronic Active					1 [3.0]	
Uterus	(53)	(53)	(53)	(52)	(52)	(53)
Adenomyosis	1 [2.0]			1 [2.0]	1 [3.0]	
Cyst		1 [3.0]			1 [2.0]	
Hemorrhage					1 [2.0]	2 [2.5]
Inflammation, Chronic Active		5 [2.6]	3 [2.3]	3 [3.3]	4 [3.0]	3 [2.3]
Inflammation, Suppurative	3 [1.7]	6 [1.3]	1 [1.0]	7 [1.4]	3 [1.7]	4 [1.0]
Metaplasia, Squamous	17 [1.8]	25 [1.8]	21 [1.8]	36 [1.8]	31 [1.9]	35 [1.9]
Ulcer				1 [3.0]	3 [2.7]	1 [2.0]
Cervix, Cyst						1 [3.0]
Endometrium, Hyperplasia, Cystic	31 [2.4]	29 [2.1]	29 [2.1]	33 [2.2]	39 [2.2]	37 [2.1]
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(53)	(53)	(53)	(53)	(53)
Atrophy			2 [2.0]			
Hyperplasia	38 [2.8]	32 [2.9]	37 [3.1]	35 [2.9]	42 [2.9]	41 [2.8]
Hyperplasia, Reticulum Cell				1 [3.0]		
Lymph Node	(5)	(4)	(4)	(4)	(3)	(7)
Hyperplasia, Plasma Cell						1 [2.0]
Iliac, Ectasia		1 [3.0]				
Lumbar, Ectasia	2 [2.0]	1 [3.0]			1 [2.0]	
Lumbar, Hemorrhage	2 [2.5]	1 [2.0]				
Lumbar, Hyperplasia, Histiocytic				1 [2.0]	1 [2.0]	
Lumbar, Hyperplasia, Plasma Cell		1 [3.0]	1 [3.0]	1 [3.0]		1 [2.0]
Mediastinal, Ectasia					2 [1.5]	2 [2.0]
Mediastinal, Hemorrhage			1 [2.0]			1 [1.0]
Mediastinal, Hyperplasia, Lymphoid			1 [2.0]			
Mediastinal, Hyperplasia, Plasma Cell		1 [3.0]		1 [3.0]	1 [3.0]	2 [1.5]
Popliteal, Ectasia	1 [2.0]					
Lymph Node, Mandibular	(53)	(53)	(51)	(53)	(51)	(51)
Congestion			1 [2.0]			
Ectasia		1 [2.0]	2 [2.0]	1 [2.0]	1 [2.0]	1 [2.0]
Hyperplasia, Histiocytic		1 [2.0]				
Hyperplasia, Lymphoid				1 [3.0]		1 [4.0]
Hyperplasia, Plasma Cell	38 [2.1]	40 [2.2]	38 [2.1]	31 [2.1]	30 [2.2]	29 [2.2]
Lymph Node, Mesenteric	(53)	(53)	(53)	(52)	(52)	(53)
Atrophy				1 [3.0]		
Hemorrhage	1 [2.0]		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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
HEMATOPOIETIC SYSTEM - CONT						
Hyperplasia, Histiocytic						1 [2.0]
Hyperplasia, Lymphoid		1 [3.0]	1 [2.0]			1 [3.0]
Hyperplasia, Plasma Cell		1 [2.0]				1 [2.0]
Spleen	(53)	(53)	(53)	(52)	(52)	(51)
Accessory Spleen	1		1			
Congestion		1 [2.0]			1 [3.0]	
Hematopoietic Cell Proliferation	49 [2.0]	49 [2.2]	48 [2.3]	51 [1.9]	46 [2.2]	50 [2.0]
Hemorrhage		1 [2.0]				
Infarct			1 [2.0]			
Necrosis		1 [3.0]				
Pigmentation	52 [1.7]	45 [1.6]	50 [1.9]	48 [1.8]	49 [1.9]	51 [1.9]
Lymphatic, Angiectasis			1 [2.0]			
Lymphoid Follicle, Atrophy	7 [2.0]	8 [2.1]	7 [2.3]	6 [2.7]	12 [2.4]	4 [2.3]
Red Pulp, Atrophy	2 [2.0]					
Red Pulp, Hyperplasia		1 [3.0]				
Thymus	(53)	(49)	(50)	(52)	(49)	(51)
Atrophy	43 [2.3]	36 [2.6]	36 [2.7]	44 [2.8]	39 [3.1]	48 [3.6]
Hemorrhage	1 [2.0]		1 [2.0]		1 [2.0]	1 [2.0]
Hyperplasia, Lymphoid			1 [2.0]			
Inflammation		1 [3.0]				
INTEGUMENTARY SYSTEM						
Mammary Gland	(53)	(53)	(53)	(53)	(53)	(53)
Cyst	1 [3.0]	2 [2.5]		5 [2.2]	4 [2.5]	3 [2.3]
Hyperplasia	33 [1.3]	29 [1.3]	26 [1.5]	20 [1.6]	20 [1.2]	17 [1.1]
Inflammation, Granulomatous	2 [1.5]	4 [2.3]	3 [2.0]	4 [2.0]	4 [2.0]	3 [2.0]
Skin	(53)	(53)	(53)	(53)	(53)	(53)
Inflammation	2 [3.0]	1 [3.0]				
Ulcer	2 [3.0]	1 [3.0]				
Conjunctiva, Inflammation						1 [2.0]
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
Brain	(53)	(53)	(53)	(53)	(53)	(53)
Edema				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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
NERVOUS SYSTEM - CONT						
Gliosis				1 [2.0]		
Hemorrhage	1 [3.0]					1 [3.0]
Hydrocephalus	1 [2.0]			1 [2.0]		1 [2.0]
Peripheral Nerve				(1)		(1)
Radicular Neuropathy						1 [2.0]
Spinal Cord				(1)		(1)
Degeneration						1 [3.0]
Hemorrhage				1 [3.0]		
Necrosis				1 [2.0]		
RESPIRATORY SYSTEM						
Lung	(53)	(53)	(53)	(53)	(53)	(52)
Edema					1 [2.0]	
Hemorrhage					1 [4.0]	
Infiltration Cellular, Histiocyte	44 [1.7]	44 [1.7]	40 [1.7]	40 [1.7]	41 [1.6]	36 [1.6]
Inflammation	5 [1.4]	8 [1.4]	7 [1.3]	6 [1.5]	7 [1.9]	8 [1.6]
Metaplasia, Squamous				2 [1.0]	4 [1.5]	3 [1.7]
Mineralization				1 [2.0]	1 [2.0]	
Alveolar Epithelium, Hyperplasia	14 [1.1]	17 [1.1]	12 [1.2]	20 [1.2]	8 [1.1]	3 [1.0]
Alveolar Epithelium, Metaplasia, Bronchiolar	5 [1.0]	6 [1.0]	5 [1.2]	9 [1.3]	23 [1.6]	28 [1.5]
Alveolus, Metaplasia, Squamous			1 [1.0]			
Nose	(53)	(53)	(53)	(53)	(53)	(53)
Inflammation	8 [1.1]	3 [1.3]	8 [1.1]	11 [1.2]	7 [1.1]	6 [1.3]
Mineralization	1 [1.0]					
Olfactory Epithelium, Metaplasia			1 [2.0]			
Respiratory Epithelium, Hyperplasia	1 [2.0]	1 [1.0]	2 [1.5]	1 [2.0]	6 [2.0]	3 [2.0]
Respiratory Epithelium, Metaplasia						1 [2.0]
Septum, Inflammation	1 [1.0]	2 [1.0]	3 [1.0]	2 [1.0]	5 [1.4]	3 [1.7]
Squamous Epithelium, Hyperplasia	1 [1.0]	1 [2.0]	1 [1.0]			
Trachea	(53)	(53)	(52)	(53)	(53)	(53)
Inflammation					1 [3.0]	1 [2.0]
Artery, Peritracheal Tissue, Inflammation, Chronic Active						1 [3.0]
Peritracheal Tissue, Inflammation		1 [3.0]	2 [3.0]	1 [3.0]		
SPECIAL SENSES SYSTEM						
Eye	(53)	(53)	(52)	(53)	(52)	(52)
Hemorrhage		1 [3.0]				
Inflammation		1 [3.0]			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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	6 NG/KG	20 NG/KG	44 NG/KG	92 NG/KG	200 NG/KG
SPECIAL SENSES SYSTEM - CONT						
Cornea, Inflammation						1 [2.0]
Lens, Degeneration		1 [3.0]				
Retina, Atrophy			1 [2.0]			
Retina, Degeneration		1 [3.0]				
Harderian Gland	(53)	(53)	(53)	(53)	(52)	(52)
Inflammation	16 [1.0]	9 [1.0]	10 [1.0]	13 [1.1]	8 [1.1]	6 [1.0]
URINARY SYSTEM						
Kidney	(53)	(53)	(53)	(52)	(53)	(53)
Accumulation, Hyaline Droplet		1 [1.0]				
Calculus Micro Observation Only	5	2	4	1	2	3
Cyst				1 [2.0]	2 [2.0]	1 [2.0]
Fibrosis						1 [3.0]
Hemorrhage					1 [2.0]	
Inflammation, Chronic Active					1 [3.0]	1 [1.0]
Inflammation, Suppurative	2 [1.0]	1 [1.0]	1 [1.0]	3 [1.0]	2 [1.0]	2 [1.5]
Mineralization	37 [1.0]	45 [1.0]	42 [1.0]	43 [1.1]	43 [1.0]	31 [1.1]
Necrosis					2 [2.5]	
Nephropathy	34 [1.1]	39 [1.2]	35 [1.2]	42 [1.4]	36 [1.4]	45 [1.5]
Pigmentation	2 [2.0]					
Artery, Inflammation, Chronic Active				1 [3.0]	1 [2.0]	
Capsule, Hemorrhage	1 [3.0]					
Pelvis, Dilatation		1 [3.0]			2 [2.0]	1 [3.0]
Pelvis, Inflammation	1 [2.0]	1 [2.0]			5 [2.0]	1 [2.0]
Renal Tubule, Dilatation			1 [2.0]			
Renal Tubule, Hyperplasia			1 [1.0]			
Renal Tubule, Necrosis		1 [2.0]				
Renal Tubule, Nephropathy						1 [1.0]
Transitional Epithelium, Hyperplasia	2 [1.0]	2 [1.5]	1 [1.0]	2 [1.0]	6 [2.7]	5 [2.0]
Urinary Bladder	(53)	(52)	(53)	(53)	(51)	(53)
Infiltration Cellular, Lymphoid						1 [3.0]
Inflammation	2 [2.5]	3 [1.7]	1 [2.0]	1 [1.0]	6 [1.5]	1 [2.0]
Transitional Epithelium, Hyperplasia		1 [2.0]			4 [2.5]	4 [1.5]
Transitional Epithelium, Metaplasia, Squamous					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]
TOXIC EQUIVALENCY FACTOR EVALUATION(PECDF)

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
DISPOSITION SUMMARY	
Animals Initially In Study	50
Early Deaths	
Moribund Sacrifice	25
Natural Death	10
Survivors	
Terminal Sacrifice	15
Animals Examined Microscopically	50
ALIMENTARY SYSTEM	
Intestine Large, Rectum	(50)
Parasite Metazoan	2
Liver	(50)
Angiectasis	1 [2.0]
Basophilic Focus	9
Basophilic Focus, Multiple	4
Cholangiofibrosis	3 [2.7]
Clear Cell Focus	4
Clear Cell Focus, Multiple	2
Degeneration, Cystic	1 [2.0]
Eosinophilic Focus	8
Eosinophilic Focus, Multiple	14
Fatty Change, Diffuse	6 [1.2]
Fatty Change, Focal	7 [1.1]
Hematopoietic Cell Proliferation	31 [1.1]
Hepatodiaphragmatic Nodule	1
Inflammation	48 [1.1]
Mixed Cell Focus	5
Mixed Cell Focus, Multiple	19
Necrosis	11 [2.1]
Pigmentation	48 [1.6]
Toxic Hepatopathy	9 [1.0]
Bile Duct, Cyst	2 [2.0]
Bile Duct, Fibrosis	1 [1.0]
Bile Duct, Hyperplasia	1 [2.0]
Centrilobular, Degeneration	7 [2.4]
Hepatocyte, Hypertrophy	14 [1.0]
Hepatocyte, Multinucleated	25 [1.2]
Oval Cell, Hyperplasia	3 [1.0]
Mesentery	(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)

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
ALIMENTARY SYSTEM - CONT	
Inflammation, Chronic Active	1 [3.0]
Necrosis	1 [3.0]
Oral Mucosa	(50)
Gingival, Hyperplasia, Squamous	14 [1.2]
Pancreas	(49)
Acinus, Vacuolization Cytoplasmic	2 [1.0]
Artery, Inflammation, Chronic Active	1 [2.0]
Stomach, Forestomach	(50)
Erosion	1 [2.0]
Hyperkeratosis	1 [2.0]
Hyperplasia, Squamous	5 [2.2]
Inflammation	1 [3.0]
Ulcer	1 [2.0]
Stomach, Glandular	(50)
Mineralization	3 [1.3]
Tooth	(24)
Peridontal Tissue, Inflammation	24 [1.2]
CARDIOVASCULAR SYSTEM	
Heart	(50)
Cardiomyopathy	13 [1.1]
ENDOCRINE SYSTEM	
Adrenal Cortex	(48)
Angiectasis	29 [1.4]
Degeneration, Cystic	12 [1.8]
Hyperplasia	7 [2.3]
Hypertrophy	36 [2.1]
Necrosis	3 [2.3]
Vacuolization Cytoplasmic	10 [1.3]
Bilateral, Inflammation, Chronic Active	1 [3.0]
Adrenal Medulla	(48)
Hyperplasia	7 [1.9]
Parathyroid Gland	(47)
Fibrosis	1 [3.0]
Pituitary Gland	(49)
Angiectasis	13 [2.3]
Cyst	1 [3.0]
Cytoplasmic Alteration	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)

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
ENDOCRINE SYSTEM - CONT	
Vacuolization Cytoplasmic	2 [1.5]
Pars Distalis, Hyperplasia	19 [2.6]
Thyroid Gland	(48)
C-Cell, Hyperplasia	15 [1.7]
Follicular Cell, Hypertrophy	23 [1.3]
GENERAL BODY SYSTEM	
None	
GENITAL SYSTEM	
Clitoral Gland	(50)
Inflammation	48 [1.8]
Duct, Cyst	39 [2.3]
Ovary	(47)
Atrophy	39 [4.0]
Cyst	12 [2.3]
Uterus	(49)
Congestion	1 [2.0]
Hemorrhage	1 [2.0]
Inflammation, Chronic Active	7 [1.9]
Inflammation, Suppurative	3 [1.3]
Metaplasia, Squamous	28 [2.1]
Endometrium, Hyperplasia, Cystic	35 [2.5]
HEMATOPOIETIC SYSTEM	
Bone Marrow	(50)
Hyperplasia	43 [3.0]
Lymph Node	(3)
Iliac, Ectasia	1 [3.0]
Iliac, Hyperplasia, Plasma Cell	1 [3.0]
Lumbar, Ectasia	1 [2.0]
Lumbar, Hyperplasia, Plasma Cell	1 [3.0]
Renal, Ectasia	1 [2.0]
Renal, Hyperplasia, Plasma Cell	1 [2.0]
Lymph Node, Mandibular	(49)
Ectasia	1 [2.0]
Hyperplasia, Lymphoid	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)

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
HEMATOPOIETIC SYSTEM - CONT	
Hyperplasia, Plasma Cell	29 [2.0]
Spleen	(49)
Hematopoietic Cell Proliferation	49 [2.2]
Pigmentation	48 [1.7]
Lymphoid Follicle, Atrophy	2 [2.0]
Thymus	(49)
Atrophy	44 [2.9]
Hemorrhage	1 [3.0]
INTEGUMENTARY SYSTEM	
Mammary Gland	(50)
Cyst	3 [2.3]
Hyperplasia	19 [1.4]
Inflammation	1 [3.0]
Inflammation, Granulomatous	1 [2.0]
Skin	(50)
Hyperkeratosis	1 [1.0]
Lip, Inflammation, Chronic Active	1 [4.0]
MUSCULOSKELETAL SYSTEM	
Bone	(50)
Osteopetrosis	1 [2.0]
NERVOUS SYSTEM	
Brain	(49)
Mineralization	1 [1.0]
RESPIRATORY SYSTEM	
Lung	(50)
Congestion	1 [3.0]
Hemorrhage	2 [2.0]
Infiltration Cellular, Histiocyte	30 [1.4]
Inflammation	5 [1.6]
Metaplasia, Squamous	1 [3.0]
Mineralization	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)

SPRAGUE-DAWLEY RATS FEMALE	200 NG/ KG STOP
RESPIRATORY SYSTEM - CONT	
Alveolar Epithelium, Hyperplasia	6 [1.0]
Alveolar Epithelium, Metaplasia, Bronchiolar	7 [1.1]
Nose	(50)
Inflammation	7 [1.0]
Nasolacrimal Duct, Inflammation	1 [3.0]
Respiratory Epithelium, Hyperplasia	2 [2.0]
Trachea	(50)
Inflammation	1 [2.0]
SPECIAL SENSES SYSTEM	
Eye	(49)
Retina, Atrophy	1 [2.0]
Harderian Gland	(49)
Inflammation	6 [1.3]
URINARY SYSTEM	
Kidney	(48)
Accumulation, Hyaline Droplet	3 [2.0]
Calculus Micro Observation Only	1
Infarct	1 [3.0]
Inflammation	1 [4.0]
Inflammation, Suppurative	2 [1.0]
Mineralization	41 [1.0]
Nephropathy	35 [1.1]
Pelvis, Dilatation	1 [3.0]
Pelvis, Inflammation	1 [2.0]
Transitional Epithelium, Hyperplasia	3 [1.7]
Urinary Bladder	(50)
Inflammation	2 [3.0]
Transitional Epithelium, Hyperplasia	3 [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

National Toxicology Program

TR-520 Toxic Equivalency Factor Evaluation (PCB 126)

Revised Pathology Tables – Female Rats Core Study

- P03 - Incidence Rates of Non-Neoplastic Lesions
- P05 - Incidence Rates of Neoplasms by Anatomic Site (systemic lesions abridged)
- P08 - Statistical Analysis of Primary Tumors (control vs stop group)
- P08 - Statistical Analysis of Primary Tumors (control vs treated group)
- P08 - Statistical Analysis of Primary Tumors (control vs groups 3, 4, & 5)
- P08 - Statistical Analysis of Primary Tumors (control vs groups 6, 7, & 8)
- P18 - Incidence Rates of Non-Neoplastic Lesions

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

FINAL #2 RATS

Facility: Battelle Columbus Laboratory

Chemical CAS #: 57465-28-8

Lock Date: 01/09/01

Cage Range: All

Reasons For Removal:
25022 Accidently Killed
25019 Moribund Sacrifice
25021 Terminal Sacrifice
25018 Dosing Accident
25020 Natural Death

Removal Date Range: All

Treatment Groups:

Include 001	0	NG/KG
Include 003	30	NG/KG
Include 004	100	NG/KG
Include 005	175	NG/KG
Include 006	300	NG/KG
Include 007	550	NG/KG
Include 008	1000	NG/KG
Include 009	1000	NG/KG/STOP

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

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
DISPOSITION SUMMARY						
Animals Initially In Study	98	98	98	98	98	98
Early Deaths						
Moribund Sacrifice	25	18	21	19	27	18
Natural Death	10	9	6	11	9	12
Accidently Killed	1	3				
Dosing Accident	2			1	1	
Survivors						
Natural Death		1	1			
Terminal Sacrifice	15	24	25	22	16	23
Animals Examined Microscopically	53	55	53	53	53	53
ALIMENTARY SYSTEM						
Esophagus	(52)	(55)	(53)	(53)	(53)	(52)
Hemorrhage						1 (2%)
Hyperplasia, Focal, Squamous			1 (2%)			
Muscularis, Degeneration					1 (2%)	
Muscularis, Inflammation	2 (4%)	1 (2%)		1 (2%)	1 (2%)	2 (4%)
Periesophageal Tissue, Inflammation, Suppurative					1 (2%)	
Intestine Large, Colon	(52)	(55)	(53)	(53)	(53)	(51)
Hyperplasia, Adenomatous			1 (2%)			
Inflammation			1 (2%)			
Parasite Metazoan		1 (2%)	2 (4%)	1 (2%)		
Intestine Large, Rectum	(52)	(55)	(53)	(52)	(53)	(52)
Infiltration Cellular, Lymphocyte			1 (2%)			
Inflammation, Chronic Active				1 (2%)		
Mineralization		1 (2%)				
Parasite Metazoan	2 (4%)	2 (4%)	3 (6%)		1 (2%)	
Artery, Inflammation, Chronic Active				1 (2%)		
Intestine Large, Cecum	(52)	(54)	(53)	(51)	(53)	(52)
Edema		1 (2%)				
Hyperplasia, Lymphoid					1 (2%)	
Inflammation		1 (2%)				
Intestine Small, Duodenum	(52)	(55)	(52)	(53)	(53)	(51)
Erosion	1 (2%)					
Intestine Small, Ileum	(52)	(54)	(52)	(51)	(53)	(52)
Hyperplasia, Lymphoid					1 (2%)	
Mineralization		1 (2%)				
Epithelium, Hyperplasia				1 (2%)		

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
ALIMENTARY SYSTEM - CONT						
Serosa, Inflammation, Chronic Active	1 (2%)					
Liver	(53)	(55)	(53)	(53)	(53)	(51)
Angiectasis	3 (6%)	8 (15%)	4 (8%)	1 (2%)	1 (2%)	2 (4%)
Basophilic Focus	2 (4%)	4 (7%)	6 (11%)	7 (13%)	2 (4%)	3 (6%)
Basophilic Focus, Multiple	5 (9%)	6 (11%)	4 (8%)	6 (11%)	2 (4%)	2 (4%)
Cholangiofibrosis		1 (2%)	1 (2%)	1 (2%)	3 (6%)	13 (25%)
Clear Cell Focus	1 (2%)	1 (2%)				
Clear Cell Focus, Multiple	1 (2%)					
Cytoplasmic Alteration			1 (2%)	1 (2%)	1 (2%)	1 (2%)
Degeneration, Cystic					1 (2%)	1 (2%)
Eosinophilic Focus	6 (11%)	4 (7%)	7 (13%)	4 (8%)	2 (4%)	3 (6%)
Eosinophilic Focus, Multiple	5 (9%)	6 (11%)	6 (11%)	17 (32%)	15 (28%)	21 (41%)
Fatty Change, Diffuse	5 (9%)	7 (13%)	14 (26%)	22 (42%)	30 (57%)	45 (88%)
Fatty Change, Focal	2 (4%)	6 (11%)	8 (15%)	6 (11%)	3 (6%)	2 (4%)
Hematopoietic Cell Proliferation						1 (2%)
Hepatocyte, Multinucleate		2 (4%)	10 (19%)	14 (26%)	19 (36%)	46 (90%)
Hepatodiaphragmatic Nodule	1 (2%)	1 (2%)		1 (2%)		
Hyperplasia, Nodular				1 (2%)	3 (6%)	26 (51%)
Inflammation	36 (68%)	40 (73%)	49 (92%)	50 (94%)	51 (96%)	51 (100%)
Mixed Cell Focus	4 (8%)	6 (11%)	7 (13%)	3 (6%)		3 (6%)
Mixed Cell Focus, Multiple	17 (32%)	18 (33%)	25 (47%)	29 (55%)	30 (57%)	26 (51%)
Necrosis	4 (8%)	2 (4%)	5 (9%)	8 (15%)	11 (21%)	15 (29%)
Pigmentation	1 (2%)	11 (20%)	41 (77%)	39 (74%)	48 (91%)	51 (100%)
Toxic Hepatopathy		6 (11%)	22 (42%)	27 (51%)	39 (74%)	51 (100%)
Vacuolization Cytoplasmic		1 (2%)				
Artery, Inflammation, Chronic Active				1 (2%)	1 (2%)	1 (2%)
Bile Duct, Cyst	3 (6%)	6 (11%)		2 (4%)	3 (6%)	8 (16%)
Bile Duct, Fibrosis	4 (8%)	4 (7%)	3 (6%)	2 (4%)	1 (2%)	4 (8%)
Bile Duct, Hyperplasia	3 (6%)	7 (13%)	7 (13%)	13 (25%)	14 (26%)	45 (88%)
Hepatocyte, Degeneration	3 (6%)	1 (2%)	1 (2%)		1 (2%)	1 (2%)
Hepatocyte, Hypertrophy		23 (42%)	32 (60%)	36 (68%)	42 (79%)	50 (98%)
Oval Cell, Hyperplasia		1 (2%)	6 (11%)	7 (13%)	10 (19%)	38 (75%)
Portal, Fibrosis					2 (4%)	1 (2%)
Serosa, Inflammation		1 (2%)				
Mesentery	(1)		(4)	(2)	(7)	(13)
Inflammation, Chronic Active	1 (100%)					
Artery, Inflammation, Chronic Active			2 (50%)	2 (100%)	6 (86%)	10 (77%)
Fat, Necrosis			1 (25%)		1 (14%)	1 (8%)
Oral Mucosa	(1)	(1)	(3)	(4)	(2)	(6)
Gingival, Hyperplasia, Squamous	1 (100%)		2 (67%)	2 (50%)		4 (67%)
Pancreas	(51)	(55)	(53)	(53)	(53)	(52)
Basophilic Focus		1 (2%)		1 (2%)		
Cyst						1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
ALIMENTARY SYSTEM - CONT						
Inflammation, Chronic Active	5 (10%)	1 (2%)	3 (6%)	4 (8%)	4 (8%)	6 (12%)
Acinus, Atrophy	5 (10%)	3 (5%)	2 (4%)	7 (13%)	2 (4%)	11 (21%)
Acinus, Hyperplasia		1 (2%)	1 (2%)	1 (2%)	1 (2%)	
Acinus, Vacuolization Cytoplasmic			1 (2%)	4 (8%)	9 (17%)	20 (38%)
Artery, Inflammation, Chronic Active		4 (7%)	2 (4%)	4 (8%)	8 (15%)	15 (29%)
Artery, Mineralization		1 (2%)				1 (2%)
Duct, Hyperplasia						1 (2%)
Duct, Inflammation, Chronic Active						2 (4%)
Salivary Glands	(51)	(54)	(53)	(51)	(52)	(51)
Atrophy				1 (2%)	1 (2%)	
Cyst		1 (2%)			1 (2%)	
Inflammation, Acute					1 (2%)	
Inflammation, Chronic Active	1 (2%)				1 (2%)	
Stomach, Forestomach	(52)	(55)	(53)	(53)	(53)	(51)
Edema	1 (2%)		1 (2%)		1 (2%)	
Erosion		1 (2%)				
Hyperkeratosis		3 (5%)	1 (2%)	1 (2%)	3 (6%)	1 (2%)
Hyperplasia, Squamous	3 (6%)	4 (7%)	6 (11%)	2 (4%)	5 (9%)	6 (12%)
Inflammation, Acute	1 (2%)					
Inflammation, Chronic Active		1 (2%)	2 (4%)	1 (2%)	1 (2%)	
Mineralization	1 (2%)		1 (2%)	1 (2%)		1 (2%)
Necrosis, Focal			1 (2%)			
Ulcer	3 (6%)	1 (2%)		1 (2%)	3 (6%)	2 (4%)
Stomach, Glandular	(51)	(53)	(53)	(53)	(53)	(51)
Erosion	1 (2%)	1 (2%)		1 (2%)		
Metaplasia, Focal			1 (2%)			
Mineralization	1 (2%)	1 (2%)		1 (2%)		
Tooth	(12)	(12)	(10)	(9)	(10)	(9)
Peridontal Tissue, Inflammation, Chronic Active	2 (17%)					1 (11%)
Peridontal Tissue, Inflammation, Suppurative	10 (83%)	12 (100%)	10 (100%)	9 (100%)	10 (100%)	8 (89%)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(53)	(55)	(53)	(53)	(53)	(53)
Aorta, Mineralization	3 (6%)	1 (2%)	1 (2%)			2 (4%)
Heart	(52)	(54)	(53)	(53)	(53)	(51)
Cardiomyopathy	9 (17%)	16 (30%)	17 (32%)	16 (30%)	24 (45%)	28 (55%)
Degeneration	1 (2%)	1 (2%)				1 (2%)
Inflammation		1 (2%)				
Mineralization	1 (2%)	1 (2%)				1 (2%)
Thrombosis	1 (2%)					1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
CARDIOVASCULAR SYSTEM - CONT						
Artery, Inflammation, Chronic Active				1 (2%)		
Epicardium, Inflammation, Chronic Active					1 (2%)	
Epicardium, Inflammation, Suppurative	2 (4%)			1 (2%)		
Myocardium, Inflammation					1 (2%)	1 (2%)
ENDOCRINE SYSTEM						
Adrenal Cortex	(52)	(55)	(53)	(53)	(53)	(52)
Angiectasis	11 (21%)	13 (24%)	25 (47%)	19 (36%)	20 (38%)	8 (15%)
Atrophy	1 (2%)	3 (5%)	5 (9%)	3 (6%)	5 (9%)	19 (37%)
Degeneration, Cystic	11 (21%)	14 (25%)	10 (19%)	14 (26%)	14 (26%)	16 (31%)
Hyperplasia	23 (44%)	21 (38%)	27 (51%)	25 (47%)	25 (47%)	31 (60%)
Hypertrophy	34 (65%)	41 (75%)	40 (75%)	41 (77%)	40 (75%)	41 (79%)
Inflammation, Suppurative			1 (2%)			
Mineralization	1 (2%)					1 (2%)
Necrosis	1 (2%)	1 (2%)		1 (2%)	1 (2%)	1 (2%)
Thrombosis						1 (2%)
Vacuolization Cytoplasmic	5 (10%)	3 (5%)	5 (9%)	2 (4%)	9 (17%)	4 (8%)
Adrenal Medulla	(52)	(55)	(53)	(53)	(53)	(52)
Angiectasis			2 (4%)	1 (2%)	2 (4%)	2 (4%)
Hyperplasia	8 (15%)	18 (33%)	11 (21%)	11 (21%)	12 (23%)	6 (12%)
Necrosis				1 (2%)		
Islets, Pancreatic	(52)	(54)	(53)	(53)	(53)	(52)
Hyperplasia	1 (2%)	2 (4%)	1 (2%)	1 (2%)		1 (2%)
Parathyroid Gland	(47)	(50)	(48)	(46)	(49)	(47)
Hyperplasia		1 (2%)	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Pituitary Gland	(51)	(54)	(53)	(53)	(53)	(53)
Angiectasis	14 (27%)	15 (28%)	22 (42%)	12 (23%)	16 (30%)	19 (36%)
Cyst		3 (6%)	1 (2%)	1 (2%)		2 (4%)
Cytoplasmic Alteration		1 (2%)	1 (2%)	1 (2%)	3 (6%)	1 (2%)
Inflammation, Focal, Granulomatous						1 (2%)
Necrosis					1 (2%)	
Pigmentation					1 (2%)	
Vacuolization Cytoplasmic		1 (2%)	1 (2%)			
Pars Distalis, Hyperplasia	18 (35%)	20 (37%)	23 (43%)	17 (32%)	21 (40%)	26 (49%)
Thyroid Gland	(52)	(55)	(52)	(51)	(52)	(50)
Angiectasis		1 (2%)	4 (8%)			
Cyst				1 (2%)		1 (2%)
C-Cell, Hyperplasia	12 (23%)	21 (38%)	17 (33%)	19 (37%)	18 (35%)	16 (32%)
Follicle, Cyst			1 (2%)			
Follicular Cell, Hyperplasia			1 (2%)	1 (2%)		
Follicular Cell, Hypertrophy	9 (17%)	13 (24%)	13 (25%)	17 (33%)	28 (54%)	26 (52%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(50)	(55)	(52)	(50)	(53)	(52)
Hyperplasia		1 (2%)				
Hyperplasia, Squamous			1 (2%)			
Inflammation	28 (56%)	36 (65%)	39 (75%)	28 (56%)	30 (57%)	27 (52%)
Duct, Cyst	29 (58%)	32 (58%)	34 (65%)	37 (74%)	39 (74%)	42 (81%)
Ovary	(52)	(54)	(53)	(52)	(52)	(52)
Atrophy	45 (87%)	49 (91%)	46 (87%)	45 (87%)	47 (90%)	46 (88%)
Cyst	12 (23%)	17 (31%)	17 (32%)	15 (29%)	16 (31%)	18 (35%)
Inflammation, Chronic Active				1 (2%)	1 (2%)	
Inflammation, Suppurative		1 (2%)				2 (4%)
Necrosis					1 (2%)	
Artery, Inflammation, Chronic Active			1 (2%)	1 (2%)		
Oviduct	(1)	(1)			(1)	(3)
Cyst						1 (33%)
Inflammation, Chronic Active					1 (100%)	
Inflammation, Suppurative	1 (100%)	1 (100%)				2 (67%)
Uterus	(52)	(55)	(53)	(52)	(53)	(52)
Adenomyosis		1 (2%)		1 (2%)		2 (4%)
Cyst		1 (2%)				
Erosion			1 (2%)			
Hemorrhage				1 (2%)	2 (4%)	1 (2%)
Inflammation, Chronic Active				2 (4%)	1 (2%)	1 (2%)
Inflammation, Granulomatous	1 (2%)					
Inflammation, Suppurative	12 (23%)	12 (22%)	11 (21%)	16 (31%)	10 (19%)	6 (12%)
Metaplasia, Squamous	26 (50%)	33 (60%)	25 (47%)	28 (54%)	29 (55%)	27 (52%)
Thrombosis				1 (2%)		1 (2%)
Ulcer		1 (2%)				
Vacuolization Cytoplasmic			2 (4%)			
Artery, Inflammation, Chronic Active			1 (2%)			1 (2%)
Cervix, Cyst					1 (2%)	
Cervix, Hyperplasia, Stromal						1 (2%)
Endometrium, Hyperplasia, Cystic	23 (44%)	33 (60%)	28 (53%)	24 (46%)	26 (49%)	32 (62%)
Epithelium, Hyperplasia	1 (2%)			1 (2%)		
Epithelium, Necrosis			1 (2%)	1 (2%)		

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(55)	(53)	(53)	(53)	(53)
Angiectasis						1 (2%)
Fibrosis			1 (2%)			
Hyperplasia	47 (89%)	37 (67%)	35 (66%)	44 (83%)	45 (85%)	46 (87%)
Lymph Node	(2)	(6)	(6)	(6)	(4)	(7)
Ectasia				1 (17%)		
Deep Cervical, Ectasia			1 (17%)			
Inguinal, Hyperplasia, Plasma Cell			1 (17%)			
Inguinal, Pigmentation			1 (17%)			
Lumbar, Ectasia						2 (29%)
Lumbar, Hyperplasia						1 (14%)
Lumbar, Hyperplasia, Lymphoid		1 (17%)				
Lumbar, Hyperplasia, Plasma Cell				2 (33%)	1 (25%)	
Mediastinal, Ectasia		2 (33%)	3 (50%)			
Mediastinal, Hemorrhage			2 (33%)	1 (17%)	1 (25%)	
Mediastinal, Hyperplasia, Lymphoid					1 (25%)	
Mediastinal, Hyperplasia, Plasma Cell					1 (25%)	1 (14%)
Mediastinal, Inflammation, Suppurative					1 (25%)	
Pancreatic, Hyperplasia, Plasma Cell						1 (14%)
Lymph Node, Mandibular	(52)	(53)	(51)	(51)	(52)	(51)
Ectasia	1 (2%)	1 (2%)	4 (8%)	4 (8%)	4 (8%)	4 (8%)
Hemorrhage					1 (2%)	
Hyperplasia, Lymphoid		1 (2%)	1 (2%)	1 (2%)	2 (4%)	
Hyperplasia, Plasma Cell	18 (35%)	24 (45%)	31 (61%)	21 (41%)	29 (56%)	11 (22%)
Lymph Node, Mesenteric	(52)	(54)	(52)	(52)	(53)	(51)
Atrophy			1 (2%)			
Ectasia	1 (2%)					1 (2%)
Hemorrhage	2 (4%)	3 (6%)		1 (2%)	1 (2%)	
Hyperplasia, Histiocytic	3 (6%)					1 (2%)
Hyperplasia, Plasma Cell					1 (2%)	
Pigmentation						1 (2%)
Spleen	(52)	(55)	(52)	(53)	(53)	(52)
Hematopoietic Cell Proliferation	39 (75%)	43 (78%)	46 (88%)	45 (85%)	41 (77%)	42 (81%)
Hyperplasia, Lymphoid			1 (2%)		1 (2%)	1 (2%)
Necrosis		1 (2%)				
Pigmentation	49 (94%)	50 (91%)	51 (98%)	51 (96%)	52 (98%)	52 (100%)
Lymphoid Follicle, Atrophy		5 (9%)	3 (6%)	2 (4%)	5 (9%)	3 (6%)
Red Pulp, Atrophy			4 (8%)	1 (2%)	1 (2%)	
Thymus	(50)	(52)	(46)	(48)	(41)	(49)
Atrophy	37 (74%)	34 (65%)	41 (89%)	45 (94%)	36 (88%)	47 (96%)
Fibrosis			1 (2%)			
Hemorrhage	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)
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
HEMATOPOIETIC SYSTEM - CONT						
Inflammation	1 (2%)			1 (2%)		
INTEGUMENTARY SYSTEM						
Mammary Gland	(52)	(55)	(53)	(53)	(53)	(52)
Cyst	8 (15%)	3 (5%)	1 (2%)	4 (8%)	5 (9%)	1 (2%)
Fibrosis, Focal					1 (2%)	
Hyperplasia	32 (62%)	33 (60%)	30 (57%)	29 (55%)	21 (40%)	23 (44%)
Inflammation, Chronic Active	1 (2%)			2 (4%)	2 (4%)	
Inflammation, Granulomatous	2 (4%)	2 (4%)		1 (2%)		
Skin	(52)	(55)	(53)	(53)	(53)	(53)
Cyst, Squamous	1 (2%)	1 (2%)				
Ulcer			1 (2%)			
Dermis, Inflammation, Focal	1 (2%)					
Subcutaneous Tissue, Inflammation, Suppurative				1 (2%)		
MUSCULOSKELETAL SYSTEM						
Bone	(53)	(55)	(53)	(53)	(53)	(53)
Inflammation, Chronic Active	1 (2%)					
Osteopetrosis			1 (2%)		2 (4%)	
Cartilage, Hypertrophy, Focal						1 (2%)
Skeletal Muscle	(1)	(1)	(1)			
Inflammation, Chronic Active	1 (100%)					
NERVOUS SYSTEM						
Brain	(53)	(55)	(53)	(53)	(53)	(53)
Hemorrhage						1 (2%)
Hydrocephalus	1 (2%)		2 (4%)			1 (2%)
RESPIRATORY SYSTEM						
Lung	(53)	(55)	(53)	(53)	(53)	(51)
Congestion	1 (2%)	1 (2%)			1 (2%)	
Infiltration Cellular, Histiocyte	41 (77%)	49 (89%)	45 (85%)	48 (91%)	45 (85%)	49 (96%)
Inflammation, Chronic Active	5 (9%)	3 (5%)		1 (2%)	1 (2%)	
Inflammation, Granulomatous	3 (6%)		2 (4%)			

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
RESPIRATORY SYSTEM - CONT						
Inflammation, Suppurative						1 (2%)
Metaplasia, Squamous	1 (2%)		1 (2%)	2 (4%)	3 (6%)	9 (18%)
Mineralization		1 (2%)	1 (2%)			1 (2%)
Thrombosis		2 (4%)				1 (2%)
Alveolar Epithelium, Hyperplasia	12 (23%)	1 (2%)		1 (2%)	2 (4%)	
Alveolar Epithelium, Metaplasia, Bronchiolar		29 (53%)	34 (64%)	41 (77%)	39 (74%)	47 (92%)
Serosa, Fibrosis			2 (4%)			
Serosa, Inflammation, Chronic Active		1 (2%)				
Serosa, Inflammation, Suppurative	2 (4%)			1 (2%)	1 (2%)	
Vein, Thrombosis				1 (2%)		
Nose	(53)	(54)	(52)	(53)	(52)	(53)
Nasolacrimal Duct, Inflammation		1 (2%)		1 (2%)	1 (2%)	
Nasolacrimal Duct, Glands, Hyperplasia						1 (2%)
Nasolacrimal Duct, Respiratory Epithelium, Hyperplasia					1 (2%)	
Nasopharyngeal Duct, Inflammation, Suppurative	1 (2%)		1 (2%)			
Olfactory Epithelium, Inflammation, Suppurative	1 (2%)		1 (2%)			
Respiratory Epithelium, Hyperplasia	2 (4%)		1 (2%)	1 (2%)	2 (4%)	2 (4%)
Respiratory Epithelium, Inflammation, Suppurative			1 (2%)		1 (2%)	1 (2%)
Respiratory Epithelium, Metaplasia	1 (2%)				1 (2%)	
Turbinate, Cyst						1 (2%)
Turbinate, Inflammation, Suppurative	2 (4%)		1 (2%)	1 (2%)	2 (4%)	
Trachea	(53)	(55)	(53)	(53)	(53)	(52)
Inflammation	1 (2%)					
Peritracheal Tissue, Inflammation	1 (2%)					
SPECIAL SENSES SYSTEM						
Ear					(1)	
Inflammation					1 (100%)	
Eye	(51)	(55)	(53)	(53)	(53)	(52)
Atrophy			1 (2%)	1 (2%)		
Cataract					1 (2%)	1 (2%)
Edema					1 (2%)	
Anterior Chamber, Inflammation, Suppurative						1 (2%)
Anterior Chamber, Ciliary Body, Cornea, Inflammation, Suppurative			1 (2%)			
Cornea, Inflammation, Suppurative						1 (2%)
Retina, Atrophy			3 (6%)	1 (2%)		1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
SPECIAL SENSES SYSTEM - CONT						
Retina, Degeneration						1 (2%)
Harderian Gland	(53)	(53)	(53)	(53)	(53)	(52)
Inflammation	2 (4%)	3 (6%)	6 (11%)	6 (11%)	3 (6%)	3 (6%)
URINARY SYSTEM						
Kidney	(53)	(55)	(53)	(53)	(53)	(52)
Calculus Micro Observation Only			1 (2%)	1 (2%)		1 (2%)
Casts Protein	4 (8%)	3 (5%)	1 (2%)	6 (11%)		
Cyst				2 (4%)		
Inflammation, Chronic Active	2 (4%)	2 (4%)	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Inflammation, Suppurative			3 (6%)			1 (2%)
Mineralization	32 (60%)	39 (71%)	44 (83%)	44 (83%)	44 (83%)	39 (75%)
Necrosis			1 (2%)		1 (2%)	1 (2%)
Nephropathy	32 (60%)	29 (53%)	38 (72%)	35 (66%)	38 (72%)	42 (81%)
Papilla, Angiectasis					1 (2%)	
Pelvis, Dilatation	2 (4%)	1 (2%)				1 (2%)
Pelvis, Inflammation, Chronic Active		2 (4%)	2 (4%)	2 (4%)		
Pelvis, Inflammation, Suppurative	2 (4%)				3 (6%)	
Renal Tubule, Accumulation, Hyaline Droplet		1 (2%)				
Renal Tubule, Dilatation				1 (2%)		
Transitional Epithelium, Hyperplasia	4 (8%)	2 (4%)	8 (15%)	4 (8%)	8 (15%)	8 (15%)
Ureter			(1)			
Mineralization			1 (100%)			
Transitional Epithelium, Hyperplasia			1 (100%)			
Urinary Bladder	(51)	(54)	(53)	(52)	(52)	(52)
Edema				1 (2%)		
Hemorrhage				1 (2%)		
Inflammation	4 (8%)	6 (11%)	10 (19%)	6 (12%)	7 (13%)	4 (8%)
Transitional Epithelium, Hyperplasia	1 (2%)	1 (2%)	1 (2%)	2 (4%)	1 (2%)	2 (4%)

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

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
DISPOSITION SUMMARY		
Animals Initially In Study	98	50
Early Deaths		
Natural Death	12	6
Moribund Sacrifice	34	15
Dosing Accident		1
Survivors		
Terminal Sacrifice	7	28
Animals Examined Microscopically	53	50
ALIMENTARY SYSTEM		
Esophagus	(52)	(50)
Cyst	1 (2%)	
Muscularis, Inflammation		1 (2%)
Intestine Large, Colon	(53)	(50)
Parasite Metazoan	1 (2%)	
Intestine Large, Rectum	(53)	(50)
Parasite Metazoan	1 (2%)	1 (2%)
Intestine Small, Duodenum	(53)	(50)
Erosion	2 (4%)	
Ulcer	1 (2%)	
Epithelium, Hyperplasia	1 (2%)	
Intestine Small, Jejunum	(53)	(50)
Hyperplasia, Lymphoid	1 (2%)	
Liver	(53)	(50)
Angiectasis	2 (4%)	8 (16%)
Basophilic Focus	2 (4%)	7 (14%)
Basophilic Focus, Multiple	3 (6%)	9 (18%)
Cholangiofibrosis	22 (42%)	1 (2%)
Clear Cell Focus		1 (2%)
Clear Cell Focus, Multiple		4 (8%)
Cytoplasmic Alteration	1 (2%)	
Degeneration, Cystic	2 (4%)	3 (6%)
Eosinophilic Focus	6 (11%)	3 (6%)
Eosinophilic Focus, Multiple	11 (21%)	9 (18%)
Fatty Change, Diffuse	47 (89%)	12 (24%)
Fatty Change, Focal		11 (22%)
Hepatocyte, Multinucleate	49 (92%)	20 (40%)
Hepatodiaphragmatic Nodule	1 (2%)	1 (2%)
Hyperplasia, Nodular	40 (75%)	

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

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
ALIMENTARY SYSTEM - CONT		
Inflammation	51 (96%)	46 (92%)
Mixed Cell Focus	4 (8%)	1 (2%)
Mixed Cell Focus, Multiple	5 (9%)	35 (70%)
Multinucleated		1 (2%)
Necrosis	17 (32%)	4 (8%)
Pigmentation	48 (91%)	48 (96%)
Toxic Hepatopathy	49 (92%)	15 (30%)
Bile Duct, Cyst	12 (23%)	5 (10%)
Bile Duct, Fibrosis	5 (9%)	4 (8%)
Bile Duct, Hyperplasia	45 (85%)	16 (32%)
Bile Duct, Inflammation	1 (2%)	
Hepatocyte, Degeneration	7 (13%)	
Hepatocyte, Hypertrophy	49 (92%)	21 (42%)
Oval Cell, Hyperplasia	40 (75%)	1 (2%)
Portal, Fibrosis	10 (19%)	
Serosa, Inflammation	1 (2%)	
Mesentery	(11)	
Inflammation, Chronic Active	3 (27%)	
Artery, Inflammation, Chronic Active	7 (64%)	
Fat, Necrosis	1 (9%)	
Oral Mucosa	(11)	(6)
Gingival, Cyst, Squamous	1 (9%)	
Gingival, Hyperplasia, Squamous	3 (27%)	3 (50%)
Pharyngeal, Hyperplasia, Squamous		1 (17%)
Pancreas	(51)	(48)
Basophilic Focus		1 (2%)
Cyst	1 (2%)	
Inflammation, Chronic Active	13 (25%)	4 (8%)
Necrosis	1 (2%)	
Acinus, Atrophy	18 (35%)	7 (15%)
Acinus, Vacuolization Cytoplasmic	23 (45%)	1 (2%)
Artery, Inflammation, Chronic Active	11 (22%)	1 (2%)
Duct, Dilatation	2 (4%)	
Duct, Hyperplasia	1 (2%)	
Salivary Glands	(51)	(49)
Atrophy		1 (2%)
Cyst		2 (4%)
Inflammation, Acute	1 (2%)	
Stomach, Forestomach	(53)	(50)
Edema		2 (4%)
Hyperkeratosis	2 (4%)	
Hyperplasia, Squamous	8 (15%)	2 (4%)
Mineralization	2 (4%)	

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

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
ALIMENTARY SYSTEM - CONT		
Ulcer	2 (4%)	
Stomach, Glandular	(53)	(50)
Erosion		1 (2%)
Inflammation, Chronic Active	1 (2%)	
Mineralization	1 (2%)	
Artery, Inflammation, Chronic Active	1 (2%)	
Glands, Ectasia	1 (2%)	
Glands, Hyperplasia	1 (2%)	
Tooth	(19)	(12)
Peridontal Tissue, Fibrosis	1 (5%)	1 (8%)
Peridontal Tissue, Inflammation, Suppurative	18 (95%)	11 (92%)
CARDIOVASCULAR SYSTEM		
Blood Vessel	(53)	(50)
Aorta, Mineralization		1 (2%)
Heart	(51)	(50)
Cardiomyopathy	32 (63%)	15 (30%)
Mineralization		1 (2%)
Thrombosis	1 (2%)	1 (2%)
Artery, Inflammation, Chronic Active		1 (2%)
Endocardium, Myocardium, Inflammation, Acute	1 (2%)	
Epicardium, Inflammation, Chronic Active	1 (2%)	
Epicardium, Inflammation, Suppurative		1 (2%)
ENDOCRINE SYSTEM		
Adrenal Cortex	(53)	(50)
Angiectasis	1 (2%)	14 (28%)
Atrophy	30 (57%)	9 (18%)
Degeneration, Cystic	10 (19%)	20 (40%)
Hyperplasia	24 (45%)	26 (52%)
Hypertrophy	41 (77%)	42 (84%)
Inflammation, Suppurative		1 (2%)
Mineralization	1 (2%)	
Necrosis	2 (4%)	2 (4%)
Vacuolization Cytoplasmic	17 (32%)	6 (12%)
Adrenal Medulla	(53)	(50)
Hyperplasia	1 (2%)	9 (18%)
Parathyroid Gland	(46)	(44)
Cyst		1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
ENDOCRINE SYSTEM - CONT		
Hyperplasia		2 (5%)
Pituitary Gland	(53)	(48)
Angiectasis	9 (17%)	14 (29%)
Cyst	1 (2%)	1 (2%)
Cytoplasmic Alteration		1 (2%)
Pars Distalis, Hyperplasia	17 (32%)	17 (35%)
Thyroid Gland	(48)	(47)
Angiectasis		1 (2%)
Atrophy	1 (2%)	
Infiltration Cellular, Lymphocyte	1 (2%)	
C-Cell, Hyperplasia	19 (40%)	18 (38%)
Follicular Cell, Hyperplasia	1 (2%)	
Follicular Cell, Hypertrophy	16 (33%)	22 (47%)
GENERAL BODY SYSTEM		
None		
GENITAL SYSTEM		
Clitoral Gland	(51)	(48)
Inflammation	22 (43%)	32 (67%)
Duct, Cyst	45 (88%)	39 (81%)
Ovary	(53)	(50)
Atrophy	33 (62%)	47 (94%)
Cyst	11 (21%)	17 (34%)
Oviduct	(1)	(2)
Inflammation, Suppurative	1 (100%)	2 (100%)
Uterus	(53)	(50)
Hemorrhage	1 (2%)	
Inflammation, Chronic Active		1 (2%)
Inflammation, Suppurative	4 (8%)	11 (22%)
Metaplasia, Squamous	11 (21%)	28 (56%)
Endometrium, Hyperplasia, Cystic	9 (17%)	31 (62%)
Epithelium, Hyperplasia		1 (2%)
Vagina	(1)	
Cyst	1 (100%)	
HEMATOPOIETIC SYSTEM		

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

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
HEMATOPOIETIC SYSTEM - CONT		
Bone Marrow	(53)	(50)
Atrophy	1 (2%)	
Hyperplasia	46 (87%)	34 (68%)
Lymph Node	(12)	(2)
Iliac, Ectasia		1 (50%)
Mediastinal, Angiectasis	1 (8%)	
Mediastinal, Ectasia	5 (42%)	
Mediastinal, Hemorrhage	6 (50%)	
Mediastinal, Hyperplasia, Lymphoid	1 (8%)	
Mediastinal, Pigmentation	2 (17%)	
Pancreatic, Hemorrhage	1 (8%)	
Lymph Node, Mandibular	(51)	(49)
Atrophy	1 (2%)	
Ectasia	3 (6%)	3 (6%)
Hemorrhage	1 (2%)	
Hyperplasia, Lymphoid	1 (2%)	
Hyperplasia, Plasma Cell	15 (29%)	21 (43%)
Lymph Node, Mesenteric	(53)	(50)
Atrophy	1 (2%)	2 (4%)
Ectasia	1 (2%)	
Hemorrhage	2 (4%)	
Hyperplasia, Histiocytic	1 (2%)	1 (2%)
Hyperplasia, Lymphoid	2 (4%)	
Hyperplasia, Plasma Cell		1 (2%)
Spleen	(52)	(50)
Hematopoietic Cell Proliferation	37 (71%)	37 (74%)
Hyperplasia, Lymphoid	3 (6%)	
Pigmentation	50 (96%)	50 (100%)
Lymphoid Follicle, Atrophy	6 (12%)	4 (8%)
Red Pulp, Atrophy	2 (4%)	
Thymus	(44)	(43)
Atrophy	41 (93%)	39 (91%)
INTEGUMENTARY SYSTEM		
Mammary Gland	(53)	(50)
Cyst	1 (2%)	13 (26%)
Hyperplasia	9 (17%)	22 (44%)
Skin	(53)	(50)
Cyst, Squamous	1 (2%)	2 (4%)

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

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/KG/STOP
MUSCULOSKELETAL SYSTEM		
Skeletal Muscle	(1)	
Inflammation, Chronic Active	1 (100%)	
NERVOUS SYSTEM		
Brain	(53)	(50)
Hemorrhage	1 (2%)	
Inflammation, Focal, Suppurative	1 (2%)	
Necrosis, Focal	1 (2%)	
RESPIRATORY SYSTEM		
Lung	(51)	(50)
Hemorrhage	1 (2%)	1 (2%)
Infiltration Cellular, Histiocyte	42 (82%)	42 (84%)
Inflammation, Chronic Active	2 (4%)	
Metaplasia, Squamous	4 (8%)	
Mineralization	1 (2%)	1 (2%)
Alveolar Epithelium, Metaplasia, Bronchiolar	40 (78%)	32 (64%)
Serosa, Inflammation, Suppurative		1 (2%)
Nose	(53)	(50)
Goblet Cell, Respiratory Epithelium, Hyperplasia	1 (2%)	
Nasolacrimal Duct, Inflammation	1 (2%)	1 (2%)
Nasolacrimal Duct, Respiratory Epithelium, Hyperplasia	1 (2%)	
Nasopharyngeal Duct, Respiratory Epithelium, Hyperplasia	1 (2%)	
Respiratory Epithelium, Hyperplasia	1 (2%)	1 (2%)
Turbinate, Cyst	1 (2%)	
Turbinate, Inflammation, Suppurative	4 (8%)	1 (2%)
Vomeronasal Organ, Vacuolization Cytoplasmic	1 (2%)	
SPECIAL SENSES SYSTEM		
Eye	(52)	(50)
Anterior Chamber, Inflammation, Suppurative	1 (2%)	1 (2%)
Cornea, Inflammation, Suppurative	2 (4%)	1 (2%)
Optic Nerve, Degeneration	1 (2%)	

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

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
SPECIAL SENSES SYSTEM - CONT		
Retina, Atrophy	4 (8%)	
Harderian Gland	(52)	(50)
Inflammation	6 (12%)	9 (18%)
URINARY SYSTEM		
Kidney	(53)	(50)
Casts Protein	2 (4%)	3 (6%)
Inflammation, Suppurative	2 (4%)	
Mineralization	37 (70%)	45 (90%)
Necrosis	1 (2%)	
Nephropathy	47 (89%)	38 (76%)
Papilla, Necrosis	1 (2%)	
Pelvis, Dilatation	2 (4%)	1 (2%)
Pelvis, Hemorrhage	1 (2%)	
Pelvis, Inflammation, Chronic Active	1 (2%)	1 (2%)
Pelvis, Metaplasia, Squamous	1 (2%)	
Transitional Epithelium, Hyperplasia	11 (21%)	2 (4%)
Ureter	(3)	
Inflammation	1 (33%)	
Metaplasia, Squamous	2 (67%)	
Mineralization	2 (67%)	
Transitional Epithelium, Hyperplasia	3 (100%)	
Urinary Bladder	(53)	(50)
Inflammation	6 (11%)	3 (6%)
Metaplasia, Squamous	1 (2%)	
Transitional Epithelium, Hyperplasia	2 (4%)	

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

END OF REPORT

FINAL #2 RATS

Facility: Battelle Columbus Laboratory

Chemical CAS #: 57465-28-8

Lock Date: 01/09/01

Cage Range: All

Reasons For Removal: 25022 Accidently Killed
25019 Moribund Sacrifice
25021 Terminal Sacrifice
25018 Dosing Accident
25020 Natural Death

Removal Date Range: All

Treatment Groups:

Include 001	0	NG/KG
Include 003	30	NG/KG
Include 004	100	NG/KG
Include 005	175	NG/KG
Include 006	300	NG/KG
Include 007	550	NG/KG
Include 008	1000	NG/KG
Include 009	1000	NG/KG/STOP

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
DISPOSITION SUMMARY						
Animals Initially in Study	98	98	98	98	98	98
Early Deaths						
Moribund Sacrifice	25	18	21	19	27	18
Natural Death	10	9	6	11	9	12
Accidently Killed	1	3				
Dosing Accident	2			1	1	
Survivors						
Natural Death		1	1			
Terminal Sacrifice	15	24	25	22	16	23
Animals Examined Microscopically	53	55	53	53	53	53
ALIMENTARY SYSTEM						
Intestine Large, Colon	(52)	(55)	(53)	(53)	(53)	(51)
Serosa, Carcinoma, Metastatic, Uterus		1 (2%)				
Intestine Large, Rectum	(52)	(55)	(53)	(52)	(53)	(52)
Intestine Small, Duodenum	(52)	(55)	(52)	(53)	(53)	(51)
Intestine Small, Jejunum	(52)	(54)	(53)	(53)	(53)	(51)
Leiomyosarcoma			2 (4%)			
Serosa, Carcinoma, Metastatic, Uterus		1 (2%)				
Intestine Small, Ileum	(52)	(54)	(52)	(51)	(53)	(52)
Carcinoma, Metastatic, Islets, Pancreatic			1 (2%)			
Serosa, Carcinoma, Metastatic, Uterus		1 (2%)				
Liver	(53)	(55)	(53)	(53)	(53)	(51)
Carcinoma, Metastatic, Islets, Pancreatic			1 (2%)			
Cholangiocarcinoma			1 (2%)		5 (9%)	2 (4%)
Cholangiocarcinoma, Multiple						4 (8%)
Cholangioma						1 (2%)
Hepatocellular Carcinoma				1 (2%)		
Hepatocellular Adenoma	1 (2%)	2 (4%)	1 (2%)			1 (2%)
Schwannoma Malignant, Metastatic, Heart			1 (2%)			
Mesentery	(1)		(4)	(2)	(7)	(13)
Carcinoma, Metastatic, Islets, Pancreatic			1 (25%)			
Sarcoma, Metastatic, Kidney						1 (8%)
Sarcoma Stromal, Metastatic, Uterus						1 (8%)
Oral Mucosa	(1)	(1)	(3)	(4)	(2)	(6)
Gingival, Squamous Cell Carcinoma		1 (100%)	1 (33%)	1 (25%)	2 (100%)	2 (33%)
Pancreas	(51)	(55)	(53)	(53)	(53)	(52)
Sarcoma Stromal, Metastatic, Uterus						1 (2%)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
ALIMENTARY SYSTEM - cont						
Acinus, Adenoma	1 (2%)				2 (4%)	
Acinus, Carcinoma				1 (2%)		
Salivary Glands	(51)	(54)	(53)	(51)	(52)	(51)
Carcinoma					1 (2%)	
Stomach, Forestomach	(52)	(55)	(53)	(53)	(53)	(51)
Serosa, Carcinoma, Metastatic, Uterus		1 (2%)				
Stomach, Glandular	(51)	(53)	(53)	(53)	(53)	(51)
Schwannoma Malignant, Metastatic, Heart			1 (2%)			
Serosa, Carcinoma, Metastatic, Uterus		1 (2%)				
CARDIOVASCULAR SYSTEM						
Blood Vessel	(53)	(55)	(53)	(53)	(53)	(53)
Heart	(52)	(54)	(53)	(53)	(53)	(51)
Schwannoma Benign					1 (2%)	
Schwannoma Malignant		1 (2%)	2 (4%)		2 (4%)	
ENDOCRINE SYSTEM						
Adrenal Cortex	(52)	(55)	(53)	(53)	(53)	(52)
Adenoma		1 (2%)	1 (2%)			1 (2%)
Carcinoma		1 (2%)			1 (2%)	
Schwannoma Malignant, Metastatic, Heart			1 (2%)			
Adrenal Medulla	(52)	(55)	(53)	(53)	(53)	(52)
Pheochromocytoma Malignant			1 (2%)	1 (2%)		1 (2%)
Pheochromocytoma Complex					1 (2%)	
Pheochromocytoma Benign	8 (15%)	3 (5%)	4 (8%)	2 (4%)	2 (4%)	4 (8%)
Schwannoma Malignant, Metastatic, Heart			1 (2%)			
Islets, Pancreatic	(52)	(54)	(53)	(53)	(53)	(52)
Adenoma		2 (4%)		1 (2%)		
Carcinoma			1 (2%)			
Parathyroid Gland	(47)	(50)	(48)	(46)	(49)	(47)
Adenoma		1 (2%)				1 (2%)
Pituitary Gland	(51)	(54)	(53)	(53)	(53)	(53)
Sarcoma, Metastatic, Brain		1 (2%)				
Pars Distalis, Adenoma	14 (27%)	18 (33%)	20 (38%)	16 (30%)	22 (42%)	13 (25%)
Pars Distalis, Adenoma, Multiple	1 (2%)					1 (2%)
Pars Distalis, Carcinoma				1 (2%)		1 (2%)
Pars Intermedia, Adenoma	1 (2%)	2 (4%)	1 (2%)			
Thyroid Gland	(52)	(55)	(52)	(51)	(52)	(50)
Bilateral, C-Cell, Adenoma	3 (6%)	4 (7%)	3 (6%)	2 (4%)	3 (6%)	2 (4%)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
ENDOCRINE SYSTEM - cont						
C-Cell, Adenoma	12 (23%)	11 (20%)	12 (23%)	11 (22%)	9 (17%)	10 (20%)
C-Cell, Carcinoma		1 (2%)	2 (4%)			2 (4%)
GENERAL BODY SYSTEM						
Tissue NOS						(1)
Carcinoma						1 (100%)
GENITAL SYSTEM						
Ovary	(52)	(54)	(53)	(52)	(52)	(52)
Cystadenoma						1 (2%)
Granulosa Cell Tumor Benign				1 (2%)		
Granulosa-Theca Tumor Malignant			1 (2%)			
Sarcoma Stromal, Metastatic, Uterus					1 (2%)	
Uterus	(52)	(55)	(53)	(52)	(53)	(52)
Adenoma						1 (2%)
Carcinoma		3 (5%)	1 (2%)	1 (2%)		1 (2%)
Hemangiosarcoma				1 (2%)		
Polyp Stromal	4 (8%)	5 (9%)	7 (13%)	3 (6%)	8 (15%)	5 (10%)
Sarcoma Stromal				1 (2%)	1 (2%)	2 (4%)
Sarcoma Stromal, Multiple				1 (2%)		
Schwannoma Malignant						1 (2%)
Squamous Cell Papilloma			1 (2%)			1 (2%)
Cervix, Sarcoma Stromal					1 (2%)	
Cervix, Schwannoma Malignant					1 (2%)	1 (2%)
Vagina	(1)		(1)		(1)	
Sarcoma	1 (100%)					
Sarcoma Stromal, Metastatic, Uterus					1 (100%)	
Squamous Cell Carcinoma			1 (100%)			
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(55)	(53)	(53)	(53)	(53)
Lymph Node	(2)	(6)	(6)	(6)	(4)	(7)
Lumbar, Sarcoma Stromal, Metastatic, Uterus						1 (14%)
Mediastinal, Carcinoma, Metastatic, Islets, Pancreatic			1 (17%)			
Mediastinal, Carcinoma, Metastatic, Thyroid Gland						1 (14%)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
HEMATOPOIETIC SYSTEM - cont						
Renal, Nephroblastoma, Metastatic, Kidney	1 (50%)					
Lymph Node, Mandibular	(52)	(53)	(51)	(51)	(52)	(51)
Osteosarcoma, Metastatic, Bone	1 (2%)					
Lymph Node, Mesenteric	(52)	(54)	(52)	(52)	(53)	(51)
Hemangiosarcoma	1 (2%)					
Spleen	(52)	(55)	(52)	(53)	(53)	(52)
Sarcoma Stromal, Metastatic, Uterus						1 (2%)
Schwannoma Malignant, Metastatic, Heart			1 (2%)			
Capsule, Carcinoma, Metastatic, Uterus		1 (2%)				
Thymus	(50)	(52)	(46)	(48)	(41)	(49)
Carcinoma, Metastatic, Mammary Gland	1 (2%)					
INTEGUMENTARY SYSTEM						
Mammary Gland	(52)	(55)	(53)	(53)	(53)	(52)
Adenoma	2 (4%)		2 (4%)		1 (2%)	
Carcinoma	5 (10%)	6 (11%)	9 (17%)	4 (8%)		1 (2%)
Carcinoma, Multiple	1 (2%)	1 (2%)		1 (2%)		
Fibroadenoma	18 (35%)	17 (31%)	21 (40%)	21 (40%)	26 (49%)	24 (46%)
Fibroadenoma, Multiple	21 (40%)	14 (25%)	14 (26%)	17 (32%)	13 (25%)	5 (10%)
Skin	(52)	(55)	(53)	(53)	(53)	(53)
Fibroma	1 (2%)	1 (2%)				
Fibrous Histiocytoma					1 (2%)	1 (2%)
Keratoacanthoma	1 (2%)		1 (2%)			
Squamous Cell Carcinoma						1 (2%)
Subcutaneous Tissue, Fibroma, Multiple			1 (2%)			
MUSCULOSKELETAL SYSTEM						
Bone	(53)	(55)	(53)	(53)	(53)	(53)
Osteosarcoma	1 (2%)					
Skeletal Muscle	(1)	(1)	(1)			
Carcinoma, Metastatic, Islets, Pancreatic			1 (100%)			
Rhabdomyosarcoma		1 (100%)				

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
NERVOUS SYSTEM						
Brain	(53)	(55)	(53)	(53)	(53)	(53)
Astrocytoma Malignant	2 (4%)				1 (2%)	
Carcinoma, Metastatic, Pituitary Gland				1 (2%)		1 (2%)
Medulloblastoma Mal			1 (2%)		1 (2%)	
Oligodendroglioma Malignant	1 (2%)					
Meninges, Sarcoma		1 (2%)				
RESPIRATORY SYSTEM						
Lung	(53)	(55)	(53)	(53)	(53)	(51)
Adenocarcinoma, Mucinous						1 (2%)
Alveolar/Bronchiolar Adenoma	1 (2%)			1 (2%)		
Alveolar/Bronchiolar Carcinoma		1 (2%)				
Carcinoma, Metastatic, Islets, Pancreatic			1 (2%)			
Carcinoma, Metastatic, Mammary Gland	1 (2%)		1 (2%)	1 (2%)		
Cystic Keratinizing Epithelioma					1 (2%)	3 (6%)
Cystic Keratinizing Epithelioma, Multiple						8 (16%)
Osteosarcoma, Metastatic, Bone	1 (2%)					
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla				1 (2%)		
Sarcoma, Metastatic, Kidney						1 (2%)
Sarcoma Stromal, Metastatic, Uterus						1 (2%)
Schwannoma Malignant, Metastatic, Heart			1 (2%)			
Squamous Cell Carcinoma						1 (2%)
Squamous Cell Carcinoma, Metastatic, Oral Mucosa		1 (2%)				
Mediastinum, Carcinoma, Metastatic, Mammary Gland				1 (2%)		
Nose	(53)	(54)	(52)	(53)	(52)	(53)
Osteosarcoma, Metastatic, Bone	1 (2%)					
Trachea	(53)	(55)	(53)	(53)	(53)	(52)
Peritracheal Tissue, Schwannoma Malignant, Metastatic, Heart					1 (2%)	
SPECIAL SENSES SYSTEM						
None						

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
URINARY SYSTEM						
Kidney	(53)	(55)	(53)	(53)	(53)	(52)
Hemangiosarcoma	1 (2%)					
Nephroblastoma	1 (2%)	2 (4%)	1 (2%)	1 (2%)		
Schwannoma Malignant, Metastatic, Heart			1 (2%)			
Stromal Nephroma		1 (2%)		1 (2%)	1 (2%)	1 (2%)
Transitional Epithelium, Carcinoma						1 (2%)
Urinary Bladder	(51)	(54)	(53)	(52)	(52)	(52)
Serosa, Carcinoma, Metastatic, Uterus		1 (2%)				
SYSTEMIC LESIONS						
Multiple Organs	*(53)	*(55)	*(53)	*(53)	*(53)	*(53)
Leukemia Granulocytic		1 (2%)				
Lymphoma Malignant		2 (4%)		2 (4%)	1 (2%)	1 (2%)

* Number of animals with any tissue examined microscopically

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
TUMOR SUMMARY						
Total Animals with Primary Neoplasms (b)	49	51	51	47	49	50
Total Primary Neoplasms	103	104	113	93	108	108
Total Animals with Benign Neoplasms	45	45	48	45	46	45
Total Benign Neoplasms	89	81	89	75	88	82
Total Animals with Malignant Neoplasms	13	19	18	15	16	23
Total Malignant Neoplasms	14	23	24	18	20	26
Total Animals with Metastatic Neoplasms	3	3	3	3	2	4
Total Metastatic Neoplasm	6	9	14	4	3	9
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

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
HEMATOPOIETIC SYSTEM - cont		
Spleen	(52)	(50)
Thymus	(44)	(43)
INTEGUMENTARY SYSTEM		
Mammary Gland	(53)	(50)
Carcinoma	1 (2%)	4 (8%)
Fibroadenoma	11 (21%)	15 (30%)
Fibroadenoma, Multiple		13 (26%)
Skin	(53)	(50)
Keratoacanthoma	1 (2%)	1 (2%)
MUSCULOSKELETAL SYSTEM		
Bone	(53)	(50)
Osteosarcoma		1 (2%)
NERVOUS SYSTEM		
Brain	(53)	(50)
Astrocytoma Malignant		1 (2%)
RESPIRATORY SYSTEM		
Lung	(51)	(50)
Carcinoma, Metastatic, Mammary Gland		1 (2%)
Carcinoma, Metastatic, Adrenal Cortex	1 (2%)	
Cystic Keratinizing Epithelioma	5 (10%)	
Cystic Keratinizing Epithelioma, Multiple	30 (59%)	
Squamous Cell Carcinoma	2 (4%)	
Nose	(53)	(50)
Squamous Cell Carcinoma, Metastatic, Oral Mucosa	1 (2%)	

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
SPECIAL SENSES SYSTEM		
Eye	(52)	(50)
Optic Nerve, Squamous Cell Carcinoma, Metastatic, Oral Mucosa	1 (2%)	
Harderian Gland	(52)	(50)
Squamous Cell Carcinoma, Metastatic, Oral Mucosa	1 (2%)	
URINARY SYSTEM		
Kidney	(53)	(50)
Nephroblastoma	2 (4%)	
Stromal Nephroma	1 (2%)	
SYSTEMIC LESIONS		
Multiple Organs	*(53)	*(50)
Leukemia Mononuclear	1 (2%)	
Lymphoma Malignant	2 (4%)	1 (2%)

* Number of animals with any tissue examined microscopically

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
TUMOR SUMMARY		
Total Animals with Primary Neoplasms (b)	49	44
Total Primary Neoplasms	118	89
Total Animals with Benign Neoplasms	42	41
Total Benign Neoplasms	77	76
Total Animals with Malignant Neoplasms	33	12
Total Malignant Neoplasms	41	13
Total Animals with Metastatic Neoplasms	2	1
Total Metastatic Neoplasm	5	1
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 #2 RATS CTRL VS STOP

REASONS FOR REMOVAL:
25022 Accidently Killed
25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:
INCLUDE 001 0 NG/KG
INCLUDE 009 1000 NG/KG/STOP

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 01
TEST TYPE: CHRONIC
CONT: N01-ES-75411
PATHOLOGIST: MISSING
Rats(SPRAGUE-DAWLEY)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 08:55:04

NTP C#: 96007D
CAS: 57465-28-8

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
Islets, Pancreatic
Kidney
Liver
Lung
Ovary
Pancreas
Parathyroid Gland
Pituitary Gland
Thyroid Gland

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 01
TEST TYPE: CHRONIC
CONT: N01-ES-75411
PATHOLOGIST: MISSING

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 08:55:04

NTP C#: 96007D
CAS: 57465-28-8

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TOXIC EQUIVALENCY FACTOR EVALUATION (

Female Rats

Organ	Morphology
Adrenal Cortex	Adenoma
Adrenal Medulla	Pheochromocytoma Benign
Brain	Astrocytoma Malignant
	Oligodendroglioma, Glioma, or Astrocytoma
Liver	Cholangiocarcinoma
Mammary Gland	Adenoma
	Carcinoma
	Carcinoma or Adenoma
	Fibroadenoma
	Fibroma, Fibroadenoma or Adenoma
	Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)	Squamous Cell Carcinoma
	Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma
Oral Mucosa	Squamous Cell Carcinoma
Pituitary Gland: Pars Distalis or Unspecified Site	Adenoma
Thyroid Gland: C-Cell	Adenoma
	Carcinoma or Adenoma
Uterus	Polyp Stromal
All Organs	Hemangiosarcoma
	Benign Tumors
	Malignant Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	 1000 NG/ KG/STOP
Adrenal Cortex **Adenoma**		
TUMOR RATES		
OVERALL (a)	0/52 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/31.36	2/37.75
POLY-3 PERCENT (g)	0.0%	5.3%
TERMINAL (d)	0/15 (0%)	2/28 (7%)
FIRST INCIDENCE	---	727 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.383
POLY 3		P=0.263
POLY 1.5		P=0.251
POLY 6		P=0.281
LOGISTIC REGRESSION		P=0.383
COCH-ARM / FISHERS		P=0.238
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	 1000 NG/ KG/STOP
Adrenal Medulla **Pheochromocytoma Benign**		
TUMOR RATES		
OVERALL (a)	8/52 (15%)	3/50 (6%)
POLY-3 RATE (b)	8/33.26	3/38.59
POLY-3 PERCENT (g)	24.1%	7.8%
TERMINAL (d)	3/15 (20%)	1/28 (4%)
FIRST INCIDENCE	531	537
STATISTICAL TESTS		
LIFE TABLE		P=0.028N*
POLY 3		P=0.052N
POLY 1.5		P=0.069N
POLY 6		P=0.037N*
LOGISTIC REGRESSION		P=0.069N
COCH-ARM / FISHERS		P=0.113N
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	 1000 NG/ KG/STOP
Brain Astrocytoma Malignant		
TUMOR RATES		
OVERALL (a)	2/53 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/31.82	1/37.75
POLY-3 PERCENT (g)	6.3%	2.7%
TERMINAL (d)	1/15 (7%)	1/28 (4%)
FIRST INCIDENCE	600	727 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.335N
POLY 3		P=0.425N
POLY 1.5		P=0.457N
POLY 6		P=0.388N
LOGISTIC REGRESSION		P=0.422N
COCH-ARM / FISHERS		P=0.522N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	 1000 NG/ KG/STOP
Brain Oligodendroglioma, Glioma, or Astrocytoma		
TUMOR RATES		
OVERALL (a)	3/53 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/32.80	1/37.75
POLY-3 PERCENT (g)	9.2%	2.7%
TERMINAL (d)	1/15 (7%)	1/28 (4%)
FIRST INCIDENCE	201	727 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.191N
POLY 3		P=0.246N
POLY 1.5		P=0.273N
POLY 6		P=0.215N
LOGISTIC REGRESSION		P=0.365N
COCH-ARM / FISHERS		P=0.331N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	 1000 NG/ KG/STOP
Liver		
Cholangiocarcinoma		
TUMOR RATES		
OVERALL (a)	0/53 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/31.38	2/37.75
POLY-3 PERCENT (g)	0.0%	5.3%
TERMINAL (d)	0/15 (0%)	2/28 (7%)
FIRST INCIDENCE	---	727 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.383
POLY 3		P=0.263
POLY 1.5		P=0.250
POLY 6		P=0.282
LOGISTIC REGRESSION		P=0.383
COCH-ARM / FISHERS		P=0.233
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	 1000 NG/ KG/STOP
Mammary Gland		
Adenoma		
TUMOR RATES	#	#
OVERALL (a)	2/53 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/31.38	0/37.75
POLY-3 PERCENT (g)	6.4%	0.0%
TERMINAL (d)	2/15 (13%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---
STATISTICAL TESTS		
LIFE TABLE		P=0.114N
POLY 3		P=0.184N
POLY 1.5		P=0.206N
POLY 6		P=0.161N
LOGISTIC REGRESSION		(e)
COCH-ARM / FISHERS		P=0.262N
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 1000 NG/KG/STOP
Mammary Gland Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	6/53 (11%)	4/50 (8%)
POLY-3 RATE (b)	6/32.44	4/38.65
POLY-3 PERCENT (g)	18.5%	10.4%
TERMINAL (d)	3/15 (20%)	3/28 (11%)
FIRST INCIDENCE	400	337
STATISTICAL TESTS		
LIFE TABLE		P=0.128N
POLY 3		P=0.254N
POLY 1.5		P=0.302N
POLY 6		P=0.203N
LOGISTIC REGRESSION		P=0.312N
COCH-ARM / FISHERS		P=0.408N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 1000 NG/KG/STOP
Mammary Gland Carcinoma or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	7/53 (13%)	4/50 (8%)
POLY-3 RATE (b)	7/32.44	4/38.65
POLY-3 PERCENT (g)	21.6%	10.4%
TERMINAL (d)	4/15 (27%)	3/28 (11%)
FIRST INCIDENCE	400	337
STATISTICAL TESTS		
LIFE TABLE		P=0.064N
POLY 3		P=0.159N
POLY 1.5		P=0.200N
POLY 6		P=0.118N
LOGISTIC REGRESSION		P=0.197N
COCH-ARM / FISHERS		P=0.298N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	 1000 NG/ KG/STOP
Mammary Gland Fibroadenoma		
TUMOR RATES	#	#
OVERALL (a)	39/53 (74%)	28/50 (56%)
POLY-3 RATE (b)	39/45.19	28/43.88
POLY-3 PERCENT (g)	86.3%	63.8%
TERMINAL (d)	11/15 (73%)	16/28 (57%)
FIRST INCIDENCE	309	328
STATISTICAL TESTS		
LIFE TABLE		P<0.001N**
POLY 3		P=0.009N**
POLY 1.5		P=0.010N*
POLY 6		P=0.011N*
LOGISTIC REGRESSION		P=0.012N*
COCH-ARM / FISHERS		P=0.048N*
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	 1000 NG/ KG/STOP
Mammary Gland Fibroma, Fibroadenoma or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	40/53 (75%)	28/50 (56%)
POLY-3 RATE (b)	40/45.19	28/43.88
POLY-3 PERCENT (g)	88.5%	63.8%
TERMINAL (d)	12/15 (80%)	16/28 (57%)
FIRST INCIDENCE	309	328
STATISTICAL TESTS		
LIFE TABLE		P<0.001N**
POLY 3		P=0.003N**
POLY 1.5		P=0.004N**
POLY 6		P=0.004N**
LOGISTIC REGRESSION		P=0.006N**
COCH-ARM / FISHERS		P=0.030N*
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 1000 NG/KG/STOP
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	42/53 (79%)	30/50 (60%)
POLY-3 RATE (b)	42/46.17	30/44.78
POLY-3 PERCENT (g)	91.0%	67.0%
TERMINAL (d)	12/15 (80%)	17/28 (61%)
FIRST INCIDENCE	309	328
STATISTICAL TESTS		
LIFE TABLE		P<0.001N**
POLY 3		P=0.003N**
POLY 1.5		P=0.003N**
POLY 6		P=0.004N**
LOGISTIC REGRESSION		P=0.006N**
COCH-ARM / FISHERS		P=0.028N*
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 1000 NG/KG/STOP
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	0/53 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/31.38	2/38.35
POLY-3 PERCENT (g)	0.0%	5.2%
TERMINAL (d)	0/15 (0%)	0/28 (0%)
FIRST INCIDENCE	---	618
STATISTICAL TESTS		
LIFE TABLE		P=0.322
POLY 3		P=0.266
POLY 1.5		P=0.252
POLY 6		P=0.288
LOGISTIC REGRESSION		P=0.249
COCH-ARM / FISHERS		P=0.233
ORDER RESTRICTED		(e)

	Females	
Dose	0 NG/KG	1000 NG/ KG/STOP
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma		
TUMOR RATES	#	#
OVERALL (a)	0/53 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/31.38	2/38.35
POLY-3 PERCENT (g)	0.0%	5.2%
TERMINAL (d)	0/15 (0%)	0/28 (0%)
FIRST INCIDENCE	---	618
STATISTICAL TESTS		
LIFE TABLE		P=0.322
POLY 3		P=0.266
POLY 1.5		P=0.252
POLY 6		P=0.288
LOGISTIC REGRESSION		P=0.249
COCH-ARM / FISHERS		P=0.233
ORDER RESTRICTED		(e)

	Females	
Dose	0 NG/KG	1000 NG/ KG/STOP
Oral Mucosa Squamous Cell Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	0/53 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/31.38	2/38.35
POLY-3 PERCENT (g)	0.0%	5.2%
TERMINAL (d)	0/15 (0%)	0/28 (0%)
FIRST INCIDENCE	---	618
STATISTICAL TESTS		
LIFE TABLE		P=0.322
POLY 3		P=0.266
POLY 1.5		P=0.252
POLY 6		P=0.288
LOGISTIC REGRESSION		P=0.249
COCH-ARM / FISHERS		P=0.233
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 1000 NG/KG/STOP
Pituitary Gland: Pars Distalis or Unspecified Site		
Adenoma		
TUMOR RATES		
OVERALL (a)	15/51 (29%)	17/48 (35%)
POLY-3 RATE (b)	15/32.57	17/38.87
POLY-3 PERCENT (g)	46.1%	43.7%
TERMINAL (d)	9/15 (60%)	11/27 (41%)
FIRST INCIDENCE	603	592
STATISTICAL TESTS		
LIFE TABLE		P=0.163N
POLY 3		P=0.511N
POLY 1.5		P=0.552
POLY 6		P=0.369N
LOGISTIC REGRESSION		P=0.451N
COCH-ARM / FISHERS		P=0.336
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 1000 NG/KG/STOP
Thyroid Gland: C-Cell		
Adenoma		
TUMOR RATES		
OVERALL (a)	15/52 (29%)	16/47 (34%)
POLY-3 RATE (b)	15/33.48	16/39.35
POLY-3 PERCENT (g)	44.8%	40.7%
TERMINAL (d)	8/15 (53%)	12/28 (43%)
FIRST INCIDENCE	519	502
STATISTICAL TESTS		
LIFE TABLE		P=0.109N
POLY 3		P=0.446N
POLY 1.5		P=0.571N
POLY 6		P=0.316N
LOGISTIC REGRESSION		P=0.381N
COCH-ARM / FISHERS		P=0.367
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	 1000 NG/ KG/STOP
Thyroid Gland: C-Cell Carcinoma or Adenoma		
TUMOR RATES		
OVERALL (a)	15/52 (29%)	17/47 (36%)
POLY-3 RATE (b)	15/33.48	17/39.35
POLY-3 PERCENT (g)	44.8%	43.2%
TERMINAL (d)	8/15 (53%)	13/28 (46%)
FIRST INCIDENCE	519	502
STATISTICAL TESTS		
LIFE TABLE		P=0.141N
POLY 3		P=0.535N
POLY 1.5		P=0.519
POLY 6		P=0.399N
LOGISTIC REGRESSION		P=0.456N
COCH-ARM / FISHERS		P=0.287
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	 1000 NG/ KG/STOP
Uterus Polyp Stromal		
TUMOR RATES	#	#
OVERALL (a)	4/53 (8%)	5/50 (10%)
POLY-3 RATE (b)	4/31.79	5/37.75
POLY-3 PERCENT (g)	12.6%	13.3%
TERMINAL (d)	2/15 (13%)	5/28 (18%)
FIRST INCIDENCE	660	727 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.429N
POLY 3		P=0.599
POLY 1.5		P=0.555
POLY 6		P=0.604N
LOGISTIC REGRESSION		P=0.532N
COCH-ARM / FISHERS		P=0.463
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 1000 NG/KG/STOP
All Organs Hemangiosarcoma		
TUMOR RATES	#	#
OVERALL (a)	2/53 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/31.60	0/37.75
POLY-3 PERCENT (g)	6.3%	0.0%
TERMINAL (d)	1/15 (7%)	0/28 (0%)
FIRST INCIDENCE	671	---
STATISTICAL TESTS		
LIFE TABLE		P=0.134N
POLY 3		P=0.186N
POLY 1.5		P=0.207N
POLY 6		P=0.164N
LOGISTIC REGRESSION		P=0.172N
COCH-ARM / FISHERS		P=0.262N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 1000 NG/KG/STOP
All Organs Benign Tumors		
TUMOR RATES	#	#
OVERALL (a)	45/53 (85%)	41/50 (82%)
POLY-3 RATE (b)	45/45.97	41/45.09
POLY-3 PERCENT (g)	97.9%	90.9%
TERMINAL (d)	15/15 (100%)	26/28 (93%)
FIRST INCIDENCE	309	328
STATISTICAL TESTS		
LIFE TABLE		P<0.001N**
POLY 3		P=0.120N
POLY 1.5		P=0.147N
POLY 6		P=0.130N
LOGISTIC REGRESSION		P=0.043N*
COCH-ARM / FISHERS		P=0.447N
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	Females 1000 NG/KG/STOP
All Organs Malignant Tumors		
TUMOR RATES	#	#
OVERALL (a)	13/53 (25%)	12/50 (24%)
POLY-3 RATE (b)	13/35.14	12/40.00
POLY-3 PERCENT (g)	37.0%	30.0%
TERMINAL (d)	5/15 (33%)	8/28 (29%)
FIRST INCIDENCE	176	337
STATISTICAL TESTS		
LIFE TABLE		P=0.114N
POLY 3		P=0.338N
POLY 1.5		P=0.420N
POLY 6		P=0.248N
LOGISTIC REGRESSION		P=0.481N
COCH-ARM / FISHERS		P=0.567N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 1000 NG/KG/STOP
All Organs Malignant and Benign Tumors		
TUMOR RATES	#	#
OVERALL (a)	49/53 (92%)	44/50 (88%)
POLY-3 RATE (b)	49/49.21	44/46.96
POLY-3 PERCENT (g)	99.6%	93.7%
TERMINAL (d)	15/15 (100%)	26/28 (93%)
FIRST INCIDENCE	176	328
STATISTICAL TESTS		
LIFE TABLE		P<0.001N**
POLY 3		P=0.121N
POLY 1.5		P=0.120N
POLY 6		P=0.156N
LOGISTIC REGRESSION		P=0.049N*
COCH-ARM / FISHERS		P=0.334N
ORDER RESTRICTED		(e)

(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).

FINAL #2 RATS CTRL VS TREATED

REASONS FOR REMOVAL:
25022 Accidently Killed
25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:

INCLUDE 001	0 NG/KG	
INCLUDE 003	30 NG/KG	
INCLUDE 004	100	NG/KG
INCLUDE 005	175	NG/KG
INCLUDE 006	300	NG/KG
INCLUDE 007	550	NG/KG
INCLUDE 008	1000	NG/KG

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 01
TEST TYPE: CHRONIC
CONT: N01-ES-75411
PATHOLOGIST: MISSING
Rats(SPRAGUE-DAWLEY)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 08:47:25

NTP C#: 96007D
CAS: 57465-28-8

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
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Ovary
Pancreas
Parathyroid Gland
Pituitary Gland
Salivary Glands
Thyroid Gland

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 01
TEST TYPE: CHRONIC
CONT: N01-ES-75411
PATHOLOGIST: MISSING

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 08:47:25

NTP C#: 96007D
CAS: 57465-28-8

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TOXIC EQUIVALENCY FACTOR EVALUATION (

Female Rats

Organ	Morphology
Adrenal Cortex	Adenoma
Adrenal Medulla	Pheochromocytoma Benign
	Pheochromocytoma: Benign, Complex, Malignant, NOS
Brain	Astrocytoma Malignant
	Oligodendroglioma, Glioma, or Astrocytoma
Liver	Cholangiocarcinoma
	Cholangioma
	Hepatocholangioma
Lung	Cystic Keratinizing Epithelioma
	Squamous Cell Carcinoma
Mammary Gland	Carcinoma
	Carcinoma or Adenoma
	Fibroadenoma
	Fibroma, Fibroadenoma or Adenoma
	Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)	Squamous Cell Carcinoma
	Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma
Oral Mucosa	Squamous Cell Carcinoma
Pituitary Gland: Pars Distalis or Unspecified Site	Adenoma
	Carcinoma or Adenoma
Thyroid Gland: C-Cell	Adenoma
All Organs	Hemangiosarcoma
	Benign Tumors
	Malignant Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Adrenal Cortex Adenoma							
TUMOR RATES							
OVERALL (a)	0/52 (0%)	1/55 (2%)	1/53 (2%)	0/53 (0%)	0/53 (0%)	1/52 (2%)	2/53 (4%)
POLY-3 RATE (b)	0/31.36	1/38.53	1/39.60	0/37.32	0/36.61	1/41.55	2/32.75
POLY-3 PERCENT (g)	0.0%	2.6%	2.5%	0.0%	0.0%	2.4%	6.1%
TERMINAL (d)	0/15 (0%)	1/25 (4%)	1/26 (4%)	0/22 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	727 (T)	727 (T)	---	---	722	603
STATISTICAL TESTS							
LIFE TABLE	P=0.041 *	P=0.602	P=0.610	(e)	(e)	P=0.602	P=0.276
POLY 3	P=0.103	P=0.541	P=0.546	(e)	(e)	P=0.555	P=0.245
POLY 1.5	P=0.105	P=0.527	P=0.531	(e)	(e)	P=0.536	P=0.247
POLY 6	P=0.107	P=0.561	P=0.565	(e)	(e)	P=0.576	P=0.233
LOGISTIC REGRESSION	P=0.087	P=0.602	P=0.610	(e)	(e)	P=0.609	P=0.243
COCH-ARM / FISHERS	P=0.105	P=0.514	P=0.505	(e)	(e)	P=0.500	P=0.252
ORDER RESTRICTED	P=0.080	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Adrenal Cortex Carcinoma							
TUMOR RATES							
OVERALL (a)	0/52 (0%)	1/55 (2%)	0/53 (0%)	0/53 (0%)	1/53 (2%)	0/52 (0%)	2/53 (4%)
POLY-3 RATE (b)	0/31.36	1/38.53	0/39.60	0/37.32	1/37.02	0/41.53	2/32.51
POLY-3 PERCENT (g)	0.0%	2.6%	0.0%	0.0%	2.7%	0.0%	6.2%
TERMINAL (d)	0/15 (0%)	1/25 (4%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	727 (T)	---	---	607	---	588
STATISTICAL TESTS							
LIFE TABLE	P=0.054	P=0.602	(e)	(e)	P=0.561	(e)	P=0.229
POLY 3	P=0.097	P=0.541	(e)	(e)	P=0.533	(e)	P=0.243
POLY 1.5	P=0.094	P=0.527	(e)	(e)	P=0.522	(e)	P=0.246
POLY 6	P=0.111	P=0.561	(e)	(e)	P=0.545	(e)	P=0.229
LOGISTIC REGRESSION	P=0.084	P=0.602	(e)	(e)	P=0.508	(e)	P=0.241
COCH-ARM / FISHERS	P=0.091	P=0.514	(e)	(e)	P=0.505	(e)	P=0.252
ORDER RESTRICTED	P=0.050	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
				Females			
Adrenal Medulla Pheochromocytoma Benign							
TUMOR RATES							
OVERALL (a)	8/52 (15%)	3/55 (5%)	4/53 (8%)	2/53 (4%)	2/53 (4%)	4/52 (8%)	0/53 (0%)
POLY-3 RATE (b)	8/33.26	3/38.95	4/40.27	2/37.58	2/36.68	4/42.10	0/31.91
POLY-3 PERCENT (g)	24.1%	7.7%	9.9%	5.3%	5.5%	9.5%	0.0%
TERMINAL (d)	3/15 (20%)	2/25 (8%)	2/26 (8%)	1/22 (5%)	1/16 (6%)	2/23 (9%)	0/7 (0%)
FIRST INCIDENCE	531	607	586	660	709	618	---
STATISTICAL TESTS							
LIFE TABLE	P=0.047N*	P=0.028N*	P=0.050N	P=0.020N*	P=0.031N*	P=0.047N*	P=0.018N*
POLY 3	P=0.027N*	P=0.052N	P=0.093N	P=0.025N*	P=0.027N*	P=0.081N	P=0.003N**
POLY 1.5	P=0.023N*	P=0.064N	P=0.115N	P=0.028N*	P=0.032N*	P=0.107N	P=0.003N**
POLY 6	P=0.043N*	P=0.039N*	P=0.072N	P=0.022N*	P=0.024N*	P=0.059N	P=0.005N**
LOGISTIC REGRESSION	P=0.019N*	P=0.052N	P=0.097N	P=0.025N*	P=0.026N*	P=0.087N	P=0.004N**
COCH-ARM / FISHERS	P=0.019N*	P=0.084N	P=0.170N	P=0.043N*	P=0.043N*	P=0.179N	P=0.003N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
				Females			
Adrenal Medulla Pheochromocytoma: Benign, Complex, Malignant, NOS							
TUMOR RATES							
OVERALL (a)	8/52 (15%)	3/55 (5%)	5/53 (9%)	3/53 (6%)	3/53 (6%)	5/52 (10%)	0/53 (0%)
POLY-3 RATE (b)	8/33.26	3/38.95	5/40.34	3/38.25	3/36.68	5/42.10	0/31.91
POLY-3 PERCENT (g)	24.1%	7.7%	12.4%	7.8%	8.2%	11.9%	0.0%
TERMINAL (d)	3/15 (20%)	2/25 (8%)	2/26 (8%)	1/22 (5%)	2/16 (13%)	3/23 (13%)	0/7 (0%)
FIRST INCIDENCE	531	607	586	500	709	618	---
STATISTICAL TESTS							
LIFE TABLE	P=0.068N	P=0.028N*	P=0.086N	P=0.048N*	P=0.067N	P=0.081N	P=0.018N*
POLY 3	P=0.037N*	P=0.052N	P=0.158N	P=0.055N	P=0.064N	P=0.140N	P=0.003N**
POLY 1.5	P=0.029N*	P=0.064N	P=0.191N	P=0.064N	P=0.073N	P=0.179N	P=0.003N**
POLY 6	P=0.062N	P=0.039N*	P=0.126N	P=0.050N	P=0.060N	P=0.107N	P=0.005N**
LOGISTIC REGRESSION	P=0.024N*	P=0.052N	P=0.158N	P=0.064N	P=0.056N	P=0.140N	P=0.004N**
COCH-ARM / FISHERS	P=0.024N*	P=0.084N	P=0.265N	P=0.095N	P=0.095N	P=0.277N	P=0.003N**
ORDER RESTRICTED	P=0.002N**	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Brain Astrocytoma Malignant							
TUMOR RATES							
OVERALL (a)	2/53 (4%)	0/55 (0%)	0/53 (0%)	0/53 (0%)	1/53 (2%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	2/31.82	0/38.53	0/39.60	0/37.32	1/37.19	0/42.13	0/31.91
POLY-3 PERCENT (g)	6.3%	0.0%	0.0%	0.0%	2.7%	0.0%	0.0%
TERMINAL (d)	1/15 (7%)	0/25 (0%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	600	---	---	---	541	---	---
STATISTICAL TESTS							
LIFE TABLE	P=0.259N	P=0.165N	P=0.156N	P=0.183N	P=0.448N	P=0.158N	P=0.301N
POLY 3	P=0.250N	P=0.196N	P=0.191N	P=0.202N	P=0.445N	P=0.181N	P=0.235N
POLY 1.5	P=0.250N	P=0.209N	P=0.206N	P=0.211N	P=0.464N	P=0.198N	P=0.231N
POLY 6	P=0.274N	P=0.179N	P=0.176N	P=0.196N	P=0.429N	P=0.165N	P=0.254N
LOGISTIC REGRESSION	P=0.245N	P=0.197N	P=0.194N	P=0.202N	P=0.480N	P=0.185N	P=0.240N
COCH-ARM / FISHERS	P=0.245N	P=0.238N	P=0.248N	P=0.248N	P=0.500N	P=0.248N	P=0.248N
ORDER RESTRICTED	P=0.020N*	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Brain Oligodendroglioma, Glioma, or Astrocytoma							
TUMOR RATES							
OVERALL (a)	3/53 (6%)	0/55 (0%)	0/53 (0%)	0/53 (0%)	1/53 (2%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	3/32.80	0/38.53	0/39.60	0/37.32	1/37.19	0/42.13	0/31.91
POLY-3 PERCENT (g)	9.2%	0.0%	0.0%	0.0%	2.7%	0.0%	0.0%
TERMINAL (d)	1/15 (7%)	0/25 (0%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	201	---	---	---	541	---	---
STATISTICAL TESTS							
LIFE TABLE	P=0.150N	P=0.082N	P=0.079N	P=0.093N	P=0.270N	P=0.080N	P=0.156N
POLY 3	P=0.149N	P=0.091N	P=0.088N	P=0.096N	P=0.260N	P=0.080N	P=0.121N
POLY 1.5	P=0.146N	P=0.100N	P=0.098N	P=0.101N	P=0.276N	P=0.092N	P=0.117N
POLY 6	P=0.166N	P=0.079N	P=0.077N	P=0.091N	P=0.245N	P=0.069N	P=0.138N
LOGISTIC REGRESSION	P=0.153N	P=0.128N	P=0.156N	P=0.155N	P=0.338N	P=0.177N	P=0.128N
COCH-ARM / FISHERS	P=0.144N	P=0.115N	P=0.121N	P=0.121N	P=0.309N	P=0.121N	P=0.121N
ORDER RESTRICTED	P=0.003N**	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Heart							
Schwannoma Malignant							
TUMOR RATES							
OVERALL (a)	0/52 (0%)	1/54 (2%)	2/53 (4%)	0/53 (0%)	2/53 (4%)	0/51 (0%)	0/51 (0%)
POLY-3 RATE (b)	0/31.37	1/37.81	2/40.29	0/37.32	2/36.86	0/41.13	0/30.95
POLY-3 PERCENT (g)	0.0%	2.6%	5.0%	0.0%	5.4%	0.0%	0.0%
TERMINAL (d)	0/15 (0%)	0/24 (0%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	652	602	---	680	---	---
STATISTICAL TESTS							
LIFE TABLE	P=0.299N	P=0.578	P=0.312	(e)	P=0.303	(e)	(e)
POLY 3	P=0.218N	P=0.537	P=0.296	(e)	P=0.274	(e)	(e)
POLY 1.5	P=0.234N	P=0.523	P=0.275	(e)	P=0.261	(e)	(e)
POLY 6	P=0.220N	P=0.558	P=0.325	(e)	P=0.287	(e)	(e)
LOGISTIC REGRESSION	P=0.264N	P=0.526	P=0.253	(e)	P=0.282	(e)	(e)
COCH-ARM / FISHERS	P=0.265N	P=0.509	P=0.252	(e)	P=0.252	(e)	(e)
ORDER RESTRICTED	P=0.443N	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Intestine Small: Jejunum							
Leiomyosarcoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	0/55 (0%)	2/53 (4%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	0/31.38	0/38.53	2/39.60	0/37.32	0/36.61	0/42.13	0/31.91
POLY-3 PERCENT (g)	0.0%	0.0%	5.1%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	2/26 (8%)	0/22 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	727 (T)	---	---	---	---
STATISTICAL TESTS							
LIFE TABLE	P=0.448N	(e)	P=0.365	(e)	(e)	(e)	(e)
POLY 3	P=0.265N	(e)	P=0.292	(e)	(e)	(e)	(e)
POLY 1.5	P=0.294N	(e)	P=0.272	(e)	(e)	(e)	(e)
POLY 6	P=0.260N	(e)	P=0.317	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.365	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.344N	(e)	P=0.248	(e)	(e)	(e)	(e)
ORDER RESTRICTED	P=0.412N	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Intestine Small: Site Unspecified Leiomyosarcoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	0/55 (0%)	2/53 (4%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	0/31.38	0/38.53	2/39.60	0/37.32	0/36.61	0/42.13	0/31.91
POLY-3 PERCENT (g)	0.0%	0.0%	5.1%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	2/26 (8%)	0/22 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	727 (T)	---	---	---	---
STATISTICAL TESTS							
LIFE TABLE	P=0.448N	(e)	P=0.365	(e)	(e)	(e)	(e)
POLY 3	P=0.265N	(e)	P=0.292	(e)	(e)	(e)	(e)
POLY 1.5	P=0.294N	(e)	P=0.272	(e)	(e)	(e)	(e)
POLY 6	P=0.260N	(e)	P=0.317	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.365	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.344N	(e)	P=0.248	(e)	(e)	(e)	(e)
ORDER RESTRICTED	P=0.412N	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Islets, Pancreatic Adenoma							
TUMOR RATES							
OVERALL (a)	0/52 (0%)	2/54 (4%)	0/53 (0%)	1/53 (2%)	0/53 (0%)	0/52 (0%)	1/51 (2%)
POLY-3 RATE (b)	0/31.36	2/38.32	0/39.60	1/37.32	0/36.61	0/41.53	1/30.67
POLY-3 PERCENT (g)	0.0%	5.2%	0.0%	2.7%	0.0%	0.0%	3.3%
TERMINAL (d)	0/15 (0%)	1/25 (4%)	0/26 (0%)	1/22 (5%)	0/16 (0%)	0/23 (0%)	1/7 (14%)
FIRST INCIDENCE	---	652	---	727 (T)	---	---	727 (T)
STATISTICAL TESTS							
LIFE TABLE	P=0.479	P=0.343	(e)	P=0.576	(e)	(e)	P=0.348
POLY 3	P=0.571N	P=0.283	(e)	P=0.535	(e)	(e)	P=0.496
POLY 1.5	P=0.606N	P=0.265	(e)	P=0.526	(e)	(e)	P=0.499
POLY 6	P=0.540N	P=0.312	(e)	P=0.543	(e)	(e)	P=0.481
LOGISTIC REGRESSION	P=0.575	P=0.292	(e)	P=0.576	(e)	(e)	P=0.348
COCH-ARM / FISHERS	P=0.622	P=0.257	(e)	P=0.505	(e)	(e)	P=0.495
ORDER RESTRICTED	P=0.315	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Islets, Pancreatic Carcinoma or Adenoma							
TUMOR RATES							
OVERALL (a)	0/52 (0%)	2/54 (4%)	1/53 (2%)	1/53 (2%)	0/53 (0%)	0/52 (0%)	1/51 (2%)
POLY-3 RATE (b)	0/31.36	2/38.32	1/40.08	1/37.32	0/36.61	0/41.53	1/30.67
POLY-3 PERCENT (g)	0.0%	5.2%	2.5%	2.7%	0.0%	0.0%	3.3%
TERMINAL (d)	0/15 (0%)	1/25 (4%)	0/26 (0%)	1/22 (5%)	0/16 (0%)	0/23 (0%)	1/7 (14%)
FIRST INCIDENCE	---	652	586	727 (T)	---	---	727 (T)
STATISTICAL TESTS							
LIFE TABLE	P=0.621	P=0.343	P=0.551	P=0.576	(e)	(e)	P=0.348
POLY 3	P=0.441N	P=0.283	P=0.548	P=0.535	(e)	(e)	P=0.496
POLY 1.5	P=0.476N	P=0.265	P=0.532	P=0.526	(e)	(e)	P=0.499
POLY 6	P=0.412N	P=0.312	P=0.568	P=0.543	(e)	(e)	P=0.481
LOGISTIC REGRESSION	P=0.549N	P=0.292	P=0.494	P=0.576	(e)	(e)	P=0.348
COCH-ARM / FISHERS	P=0.523N	P=0.257	P=0.505	P=0.505	(e)	(e)	P=0.495
ORDER RESTRICTED	P=0.369	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Kidney: Renal Tubule Nephroblastoma							
TUMOR RATES							
OVERALL (a)	1/53 (2%)	2/55 (4%)	1/53 (2%)	1/53 (2%)	0/53 (0%)	0/52 (0%)	2/53 (4%)
POLY-3 RATE (b)	1/32.37	2/40.46	1/40.57	1/38.09	0/36.61	0/41.53	2/33.85
POLY-3 PERCENT (g)	3.1%	4.9%	2.5%	2.6%	0.0%	0.0%	5.9%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	176	223	236	448	---	---	188
STATISTICAL TESTS							
LIFE TABLE	P=0.523	P=0.525	P=0.749N	P=0.741N	P=0.504N	P=0.496N	P=0.509
POLY 3	P=0.533	P=0.577	P=0.708N	P=0.724N	P=0.475N	P=0.451N	P=0.516
POLY 1.5	P=0.527	P=0.551	P=0.727N	P=0.735N	P=0.485N	P=0.469N	P=0.517
POLY 6	P=0.552	P=0.611	P=0.685N	P=0.713N	P=0.467N	P=0.431N	P=0.493
LOGISTIC REGRESSION	P=0.500	P=0.422	P=0.497	P=0.581	P=0.494N	P=0.849N	P=0.435
COCH-ARM / FISHERS	P=0.514	P=0.514	P=0.752N	P=0.752N	P=0.500N	P=0.505N	P=0.500
ORDER RESTRICTED	P=0.353	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	Females 100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
Liver Cholangiocarcinoma							
TUMOR RATES							
OVERALL (a)	0/53 (0%)	0/55 (0%)	1/53 (2%)	0/53 (0%)	5/53 (9%)	6/51 (12%)	22/53 (42%)
POLY-3 RATE (b)	0/31.38	0/38.53	1/39.60	0/37.32	5/36.89	6/42.75	22/36.46
POLY-3 PERCENT (g)	0.0%	0.0%	2.5%	0.0%	13.6%	14.0%	60.3%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	1/26 (4%)	0/22 (0%)	3/16 (19%)	1/23 (4%)	6/7 (86%)
FIRST INCIDENCE	---	---	727 (T)	---	659	618	562
STATISTICAL TESTS							
LIFE TABLE	P<0.001 **	(e)	P=0.610	(e)	P=0.047 *	P=0.068	P<0.001 **
POLY 3	P<0.001 **	(e)	P=0.546	(e)	P=0.045 *	P=0.040 *	P<0.001 **
POLY 1.5	P<0.001 **	(e)	P=0.530	(e)	P=0.039 *	P=0.028 *	P<0.001 **
POLY 6	P<0.001 **	(e)	P=0.565	(e)	P=0.050	P=0.060	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	(e)	P=0.610	(e)	P=0.052	P=0.026 *	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	(e)	P=0.500	(e)	P=0.028 *	P=0.012 *	P<0.001 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	Females 100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
Liver Cholangioma							
TUMOR RATES							
OVERALL (a)	0/53 (0%)	0/55 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	1/51 (2%)	2/53 (4%)
POLY-3 RATE (b)	0/31.38	0/38.53	0/39.60	0/37.32	0/36.61	1/41.43	2/31.91
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	0.0%	2.4%	6.3%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	1/23 (4%)	2/7 (29%)
FIRST INCIDENCE	---	---	---	---	---	727 (T)	727 (T)
STATISTICAL TESTS							
LIFE TABLE	P<0.001 **	(e)	(e)	(e)	(e)	P=0.585	P=0.090
POLY 3	P=0.005 **	(e)	(e)	(e)	(e)	P=0.554	P=0.239
POLY 1.5	P=0.006 **	(e)	(e)	(e)	(e)	P=0.534	P=0.243
POLY 6	P=0.005 **	(e)	(e)	(e)	(e)	P=0.576	P=0.220
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.585	P=0.090
COCH-ARM / FISHERS	P=0.007 **	(e)	(e)	(e)	(e)	P=0.490	P=0.248
ORDER RESTRICTED	P=0.021 *	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
				Females			
Liver Hepatocellular Adenoma							
TUMOR RATES							
OVERALL (a)	1/53 (2%)	2/55 (4%)	1/53 (2%)	0/53 (0%)	0/53 (0%)	1/51 (2%)	2/53 (4%)
POLY-3 RATE (b)	1/31.38	2/38.81	1/40.03	0/37.32	0/36.61	1/41.43	2/32.41
POLY-3 PERCENT (g)	3.2%	5.2%	2.5%	0.0%	0.0%	2.4%	6.2%
TERMINAL (d)	1/15 (7%)	1/25 (4%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	727 (T)	652	602	---	---	727 (T)	621
STATISTICAL TESTS							
LIFE TABLE	P=0.205	P=0.661	P=0.664N	P=0.424N	P=0.487N	P=0.664N	P=0.384
POLY 3	P=0.336	P=0.574	P=0.704N	P=0.465N	P=0.469N	P=0.695N	P=0.511
POLY 1.5	P=0.340	P=0.548	P=0.725N	P=0.475N	P=0.480N	P=0.721N	P=0.513
POLY 6	P=0.348	P=0.610	P=0.677N	P=0.457N	P=0.460N	P=0.665N	P=0.491
LOGISTIC REGRESSION	P=0.318	P=0.616	P=0.723N	(e)	(e)	P=0.664N	P=0.471
COCH-ARM / FISHERS	P=0.344	P=0.514	P=0.752N	P=0.500N	P=0.500N	P=0.743	P=0.500
ORDER RESTRICTED	P=0.336	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
				Females			
Liver Hepatocellular Carcinoma or Hepatocellular Adenoma							
TUMOR RATES							
OVERALL (a)	1/53 (2%)	2/55 (4%)	1/53 (2%)	1/53 (2%)	0/53 (0%)	1/51 (2%)	2/53 (4%)
POLY-3 RATE (b)	1/31.38	2/38.81	1/40.03	1/37.32	0/36.61	1/41.43	2/32.41
POLY-3 PERCENT (g)	3.2%	5.2%	2.5%	2.7%	0.0%	2.4%	6.2%
TERMINAL (d)	1/15 (7%)	1/25 (4%)	0/26 (0%)	1/22 (5%)	0/16 (0%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	727 (T)	652	602	727 (T)	---	727 (T)	621
STATISTICAL TESTS							
LIFE TABLE	P=0.241	P=0.661	P=0.664N	P=0.675N	P=0.487N	P=0.664N	P=0.384
POLY 3	P=0.402	P=0.574	P=0.704N	P=0.722N	P=0.469N	P=0.695N	P=0.511
POLY 1.5	P=0.406	P=0.548	P=0.725N	P=0.732N	P=0.480N	P=0.721N	P=0.513
POLY 6	P=0.409	P=0.610	P=0.677N	P=0.711N	P=0.460N	P=0.665N	P=0.491
LOGISTIC REGRESSION	P=0.373	P=0.616	P=0.723N	P=0.675N	(e)	P=0.664N	P=0.471
COCH-ARM / FISHERS	P=0.407	P=0.514	P=0.752N	P=0.752N	P=0.500N	P=0.743	P=0.500
ORDER RESTRICTED	P=0.427	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Liver Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma							
TUMOR RATES							
OVERALL (a)	1/53 (2%)	2/55 (4%)	1/53 (2%)	1/53 (2%)	0/53 (0%)	1/51 (2%)	2/53 (4%)
POLY-3 RATE (b)	1/31.38	2/38.81	1/40.03	1/37.32	0/36.61	1/41.43	2/32.41
POLY-3 PERCENT (g)	3.2%	5.2%	2.5%	2.7%	0.0%	2.4%	6.2%
TERMINAL (d)	1/15 (7%)	1/25 (4%)	0/26 (0%)	1/22 (5%)	0/16 (0%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	727 (T)	652	602	727 (T)	---	727 (T)	621
STATISTICAL TESTS							
LIFE TABLE	P=0.241	P=0.661	P=0.664N	P=0.675N	P=0.487N	P=0.664N	P=0.384
POLY 3	P=0.402	P=0.574	P=0.704N	P=0.722N	P=0.469N	P=0.695N	P=0.511
POLY 1.5	P=0.406	P=0.548	P=0.725N	P=0.732N	P=0.480N	P=0.721N	P=0.513
POLY 6	P=0.409	P=0.610	P=0.677N	P=0.711N	P=0.460N	P=0.665N	P=0.491
LOGISTIC REGRESSION	P=0.373	P=0.616	P=0.723N	P=0.675N	(e)	P=0.664N	P=0.471
COCH-ARM / FISHERS	P=0.407	P=0.514	P=0.752N	P=0.752N	P=0.500N	P=0.743	P=0.500
ORDER RESTRICTED	P=0.427	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Liver Hepatocholangioma							
TUMOR RATES							
OVERALL (a)	0/53 (0%)	0/55 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	0/51 (0%)	2/53 (4%)
POLY-3 RATE (b)	0/31.38	0/38.53	0/39.60	0/37.32	0/36.61	0/41.43	2/32.40
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.2%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	---	660
STATISTICAL TESTS							
LIFE TABLE	P=0.002 **	(e)	(e)	(e)	(e)	(e)	P=0.206
POLY 3	P=0.007 **	(e)	(e)	(e)	(e)	(e)	P=0.243
POLY 1.5	P=0.006 **	(e)	(e)	(e)	(e)	(e)	P=0.245
POLY 6	P=0.009 **	(e)	(e)	(e)	(e)	(e)	P=0.228
LOGISTIC REGRESSION	P=0.005 **	(e)	(e)	(e)	(e)	(e)	P=0.233
COCH-ARM / FISHERS	P=0.006 **	(e)	(e)	(e)	(e)	(e)	P=0.248
ORDER RESTRICTED	P=0.005 **	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Lung							
Cystic Keratinizing Epithelioma							
TUMOR RATES							
OVERALL (a)	0/53 (0%)	0/55 (0%)	0/53 (0%)	0/53 (0%)	1/53 (2%)	11/51 (22%)	35/51 (69%)
POLY-3 RATE (b)	0/31.38	0/38.53	0/39.60	0/37.32	1/36.61	11/42.26	35/41.94
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	2.7%	26.0%	83.5%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	0/22 (0%)	1/16 (6%)	5/23 (22%)	6/7 (86%)
FIRST INCIDENCE	---	---	---	---	727 (T)	588	484
STATISTICAL TESTS							
LIFE TABLE	P<0.001 **	(e)	(e)	(e)	P=0.513	P=0.009 **	P<0.001 **
POLY 3	P<0.001 **	(e)	(e)	(e)	P=0.531	P=0.002 **	P<0.001 **
POLY 1.5	P<0.001 **	(e)	(e)	(e)	P=0.520	P<0.001 **	P<0.001 **
POLY 6	P<0.001 **	(e)	(e)	(e)	P=0.540	P=0.005 **	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	(e)	(e)	(e)	P=0.513	P=0.004 **	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	(e)	(e)	(e)	P=0.500	P<0.001 **	P<0.001 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Lung							
Squamous Cell Carcinoma							
TUMOR RATES							
OVERALL (a)	0/53 (0%)	0/55 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	1/51 (2%)	2/51 (4%)
POLY-3 RATE (b)	0/31.38	0/38.53	0/39.60	0/37.32	0/36.61	1/41.13	2/31.91
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	0.0%	2.4%	6.3%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	727 (T)	555
STATISTICAL TESTS							
LIFE TABLE	P=0.003 **	(e)	(e)	(e)	(e)	P=0.585	P=0.265
POLY 3	P=0.005 **	(e)	(e)	(e)	(e)	P=0.553	P=0.239
POLY 1.5	P=0.005 **	(e)	(e)	(e)	(e)	P=0.532	P=0.238
POLY 6	P=0.005 **	(e)	(e)	(e)	(e)	P=0.575	P=0.229
LOGISTIC REGRESSION	P=0.006 **	(e)	(e)	(e)	(e)	P=0.585	P=0.230
COCH-ARM / FISHERS	P=0.006 **	(e)	(e)	(e)	(e)	P=0.490	P=0.238
ORDER RESTRICTED	P=0.021 *	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Mammary Gland Adenoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	2/53 (4%)	0/55 (0%)	2/53 (4%)	0/53 (0%)	1/53 (2%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	2/31.38	0/38.53	2/40.21	0/37.32	1/36.61	0/42.13	0/31.91
POLY-3 PERCENT (g)	6.4%	0.0%	5.0%	0.0%	2.7%	0.0%	0.0%
TERMINAL (d)	2/15 (13%)	0/25 (0%)	1/26 (4%)	0/22 (0%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	727 (T)	---	533	---	727 (T)	---	---
STATISTICAL TESTS							
LIFE TABLE	P=0.188N	P=0.134N	P=0.523N	P=0.157N	P=0.477N	P=0.149N	P=0.416N
POLY 3	P=0.125N	P=0.193N	P=0.602N	P=0.200N	P=0.446N	P=0.178N	P=0.232N
POLY 1.5	P=0.128N	P=0.208N	P=0.636N	P=0.210N	P=0.465N	P=0.197N	P=0.229N
POLY 6	P=0.134N	P=0.174N	P=0.560N	P=0.190N	P=0.429N	P=0.160N	P=0.248N
LOGISTIC REGRESSION	P=0.137N	(e)	P=0.608N	(e)	P=0.477N	(e)	(e)
COCH-ARM / FISHERS	P=0.137N	P=0.238N	P=0.691N	P=0.248N	P=0.500N	P=0.248N	P=0.248N
ORDER RESTRICTED	P=0.070N	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Mammary Gland Carcinoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	6/53 (11%)	7/55 (13%)	9/53 (17%)	5/53 (9%)	0/53 (0%)	1/53 (2%)	1/53 (2%)
POLY-3 RATE (b)	6/32.44	7/39.35	9/40.77	5/38.47	0/36.61	1/42.13	1/32.91
POLY-3 PERCENT (g)	18.5%	17.8%	22.1%	13.0%	0.0%	2.4%	3.0%
TERMINAL (d)	3/15 (20%)	3/25 (12%)	6/26 (23%)	3/22 (14%)	0/16 (0%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	400	580	533	496	---	727 (T)	72
STATISTICAL TESTS							
LIFE TABLE	P=0.005N**	P=0.397N	P=0.557N	P=0.299N	P=0.012N*	P=0.015N*	P=0.160N
POLY 3	P<0.001N**	P=0.591N	P=0.466	P=0.379N	P=0.009N**	P=0.024N*	P=0.049N*
POLY 1.5	P<0.001N**	P=0.598	P=0.399	P=0.413N	P=0.011N*	P=0.032N*	P=0.048N*
POLY 6	P<0.001N**	P=0.514N	P=0.551	P=0.347N	P=0.007N**	P=0.017N*	P=0.059N
LOGISTIC REGRESSION	P<0.001N**	P=0.569N	P=0.474	P=0.397N	P=0.011N*	P=0.024N*	P=0.058N
COCH-ARM / FISHERS	P<0.001N**	P=0.529	P=0.289	P=0.500N	P=0.013N*	P=0.056N	P=0.056N
ORDER RESTRICTED	P=0.020N*	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
				Females			
Mammary Gland Carcinoma or Adenoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	7/53 (13%)	7/55 (13%)	10/53 (19%)	5/53 (9%)	1/53 (2%)	1/53 (2%)	1/53 (2%)
POLY-3 RATE (b)	7/32.44	7/39.35	10/40.77	5/38.47	1/36.61	1/42.13	1/32.91
POLY-3 PERCENT (g)	21.6%	17.8%	24.5%	13.0%	2.7%	2.4%	3.0%
TERMINAL (d)	4/15 (27%)	3/25 (12%)	7/26 (27%)	3/22 (14%)	1/16 (6%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	400	580	533	496	727 (T)	727 (T)	72
STATISTICAL TESTS							
LIFE TABLE	P=0.004N**	P=0.270N	P=0.496N	P=0.191N	P=0.022N*	P=0.006N**	P=0.117N
POLY 3	P<0.001N**	P=0.459N	P=0.493	P=0.259N	P=0.017N*	P=0.010N*	P=0.024N*
POLY 1.5	P<0.001N**	P=0.514N	P=0.419	P=0.292N	P=0.021N*	P=0.015N*	P=0.024N*
POLY 6	P<0.001N**	P=0.376N	P=0.586	P=0.228N	P=0.014N*	P=0.007N**	P=0.030N*
LOGISTIC REGRESSION	P<0.001N**	P=0.426N	P=0.522	P=0.271N	P=0.016N*	P=0.009N**	P=0.032N*
COCH-ARM / FISHERS	P<0.001N**	P=0.583N	P=0.299	P=0.380N	P=0.030N*	P=0.030N*	P=0.030N*
ORDER RESTRICTED	P=0.017N*	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
				Females			
Mammary Gland Fibroadenoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	39/53 (74%)	31/55 (56%)	35/53 (66%)	38/53 (72%)	39/53 (74%)	29/53 (55%)	11/53 (21%)
POLY-3 RATE (b)	39/45.19	31/45.30	35/47.68	38/47.78	39/48.22	29/46.84	11/35.90
POLY-3 PERCENT (g)	86.3%	68.4%	73.4%	79.5%	80.9%	61.9%	30.6%
TERMINAL (d)	11/15 (73%)	18/25 (72%)	18/26 (69%)	16/22 (73%)	10/16 (63%)	14/23 (61%)	3/7 (43%)
FIRST INCIDENCE	309	356	188	385	247	440	258
STATISTICAL TESTS							
LIFE TABLE	P=0.003N**	P=0.003N**	P=0.010N*	P=0.095N	P=0.250N	P<0.001N**	P<0.001N**
POLY 3	P<0.001N**	P=0.029N*	P=0.085N	P=0.263N	P=0.327N	P=0.004N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.027N*	P=0.095N	P=0.274N	P=0.387N	P=0.005N**	P<0.001N**
POLY 6	P<0.001N**	P=0.033N*	P=0.101N	P=0.318N	P=0.304N	P=0.006N**	P<0.001N**
LOGISTIC REGRESSION	P<0.001N**	P=0.015N*	P=0.127N	P=0.283N	P=0.445N	P=0.004N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.047N*	P=0.263N	P=0.500N	P=0.587N	P=0.034N*	P<0.001N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Mammary Gland Fibroma, Fibroadenoma or Adenoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	40/53 (75%)	31/55 (56%)	36/53 (68%)	38/53 (72%)	39/53 (74%)	29/53 (55%)	11/53 (21%)
POLY-3 RATE (b)	40/45.19	31/45.30	36/48.29	38/47.78	39/48.22	29/46.84	11/35.90
POLY-3 PERCENT (g)	88.5%	68.4%	74.6%	79.5%	80.9%	61.9%	30.6%
TERMINAL (d)	12/15 (80%)	18/25 (72%)	18/26 (69%)	16/22 (73%)	10/16 (63%)	14/23 (61%)	3/7 (43%)
FIRST INCIDENCE	309	356	188	385	247	440	258
STATISTICAL TESTS							
LIFE TABLE	P=0.002N**	P=0.002N**	P=0.009N**	P=0.070N	P=0.210N	P<0.001N**	P<0.001N**
POLY 3	P<0.001N**	P=0.013N*	P=0.058N	P=0.165N	P=0.219N	P=0.002N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.013N*	P=0.074N	P=0.182N	P=0.279N	P=0.002N**	P<0.001N**
POLY 6	P<0.001N**	P=0.014N*	P=0.062N	P=0.203N	P=0.195N	P=0.002N**	P<0.001N**
LOGISTIC REGRESSION	P<0.001N**	P=0.008N**	P=0.118N	P=0.194N	P=0.344N	P=0.002N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.029N*	P=0.259N	P=0.413N	P=0.500N	P=0.020N*	P<0.001N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	42/53 (79%)	36/55 (65%)	38/53 (72%)	39/53 (74%)	39/53 (74%)	29/53 (55%)	12/53 (23%)
POLY-3 RATE (b)	42/46.17	36/46.12	38/48.57	39/48.24	39/48.22	29/46.84	12/36.90
POLY-3 PERCENT (g)	91.0%	78.1%	78.2%	80.8%	80.9%	61.9%	32.5%
TERMINAL (d)	12/15 (80%)	19/25 (76%)	19/26 (73%)	16/22 (73%)	10/16 (63%)	14/23 (61%)	3/7 (43%)
FIRST INCIDENCE	309	356	188	385	247	440	72
STATISTICAL TESTS							
LIFE TABLE	P<0.001N**	P=0.005N**	P=0.007N**	P=0.054N	P=0.143N	P<0.001N**	P<0.001N**
POLY 3	P<0.001N**	P=0.064N	P=0.064N	P=0.114N	P=0.121N	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.056N	P=0.073N	P=0.122N	P=0.149N	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.072N	P=0.075N	P=0.149N	P=0.118N	P<0.001N**	P<0.001N**
LOGISTIC REGRESSION	P<0.001N**	P=0.023N*	P=0.104N	P=0.134N	P=0.191N	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.083N	P=0.249N	P=0.324N	P=0.324N	P=0.006N**	P<0.001N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	1/55 (2%)	1/53 (2%)	1/53 (2%)	2/53 (4%)	2/53 (4%)	7/53 (13%)
POLY-3 RATE (b)	0/31.38	1/38.71	1/39.88	1/37.32	2/36.99	2/42.83	7/34.71
POLY-3 PERCENT (g)	0.0%	2.6%	2.5%	2.7%	5.4%	4.7%	20.2%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	1/22 (5%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	681	651	727 (T)	618	498	523
STATISTICAL TESTS							
LIFE TABLE	P<0.001 **	P=0.602	P=0.595	P=0.576	P=0.280	P=0.328	P=0.011 *
POLY 3	P<0.001 **	P=0.542	P=0.547	P=0.534	P=0.275	P=0.312	P=0.010 *
POLY 1.5	P<0.001 **	P=0.527	P=0.531	P=0.525	P=0.261	P=0.285	P=0.009 **
POLY 6	P<0.001 **	P=0.562	P=0.567	P=0.543	P=0.289	P=0.342	P=0.009 **
LOGISTIC REGRESSION	P<0.001 **	P=0.547	P=0.529	P=0.576	P=0.271	P=0.225	P=0.010 *
COCH-ARM / FISHERS	P<0.001 **	P=0.509	P=0.500	P=0.500	P=0.248	P=0.248	P=0.006 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	1/55 (2%)	1/53 (2%)	1/53 (2%)	2/53 (4%)	2/53 (4%)	7/53 (13%)
POLY-3 RATE (b)	0/31.38	1/38.71	1/39.88	1/37.32	2/36.99	2/42.83	7/34.71
POLY-3 PERCENT (g)	0.0%	2.6%	2.5%	2.7%	5.4%	4.7%	20.2%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	1/22 (5%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	681	651	727 (T)	618	498	523
STATISTICAL TESTS							
LIFE TABLE	P<0.001 **	P=0.602	P=0.595	P=0.576	P=0.280	P=0.328	P=0.011 *
POLY 3	P<0.001 **	P=0.542	P=0.547	P=0.534	P=0.275	P=0.312	P=0.010 *
POLY 1.5	P<0.001 **	P=0.527	P=0.531	P=0.525	P=0.261	P=0.285	P=0.009 **
POLY 6	P<0.001 **	P=0.562	P=0.567	P=0.543	P=0.289	P=0.342	P=0.009 **
LOGISTIC REGRESSION	P<0.001 **	P=0.547	P=0.529	P=0.576	P=0.271	P=0.225	P=0.010 *
COCH-ARM / FISHERS	P<0.001 **	P=0.509	P=0.500	P=0.500	P=0.248	P=0.248	P=0.006 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Oral Mucosa							
Squamous Cell Carcinoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	1/55 (2%)	1/53 (2%)	1/53 (2%)	2/53 (4%)	2/53 (4%)	7/53 (13%)
POLY-3 RATE (b)	0/31.38	1/38.71	1/39.88	1/37.32	2/36.99	2/42.83	7/34.71
POLY-3 PERCENT (g)	0.0%	2.6%	2.5%	2.7%	5.4%	4.7%	20.2%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	1/22 (5%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	681	651	727 (T)	618	498	523
STATISTICAL TESTS							
LIFE TABLE	P<0.001 **	P=0.602	P=0.595	P=0.576	P=0.280	P=0.328	P=0.011 *
POLY 3	P<0.001 **	P=0.542	P=0.547	P=0.534	P=0.275	P=0.312	P=0.010 *
POLY 1.5	P<0.001 **	P=0.527	P=0.531	P=0.525	P=0.261	P=0.285	P=0.009 **
POLY 6	P<0.001 **	P=0.562	P=0.567	P=0.543	P=0.289	P=0.342	P=0.009 **
LOGISTIC REGRESSION	P<0.001 **	P=0.547	P=0.529	P=0.576	P=0.271	P=0.225	P=0.010 *
COCH-ARM / FISHERS	P<0.001 **	P=0.509	P=0.500	P=0.500	P=0.248	P=0.248	P=0.006 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Pancreas							
Adenoma							
TUMOR RATES							
OVERALL (a)	1/51 (2%)	0/55 (0%)	0/53 (0%)	0/53 (0%)	2/53 (4%)	0/52 (0%)	0/51 (0%)
POLY-3 RATE (b)	1/31.35	0/38.53	0/39.60	0/37.32	2/36.63	0/41.53	0/30.95
POLY-3 PERCENT (g)	3.2%	0.0%	0.0%	0.0%	5.5%	0.0%	0.0%
TERMINAL (d)	1/15 (7%)	0/25 (0%)	0/26 (0%)	0/22 (0%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	727 (T)	---	---	---	722	---	---
STATISTICAL TESTS							
LIFE TABLE	P=0.600N	P=0.398N	P=0.390N	P=0.424N	P=0.536	P=0.415N	P=0.652N
POLY 3	P=0.431N	P=0.459N	P=0.454N	P=0.465N	P=0.554	P=0.445N	P=0.503N
POLY 1.5	P=0.433N	P=0.472N	P=0.469N	P=0.473N	P=0.538	P=0.463N	P=0.500N
POLY 6	P=0.463N	P=0.439N	P=0.435N	P=0.457N	P=0.572	P=0.424N	P=0.516N
LOGISTIC REGRESSION	P=0.564N	(e)	(e)	(e)	P=0.571	(e)	(e)
COCH-ARM / FISHERS	P=0.440N	P=0.481N	P=0.490N	P=0.490N	P=0.515	P=0.495N	P=0.500N
ORDER RESTRICTED	P=0.254N	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
				Females			
Pancreas Carcinoma or Adenoma							
TUMOR RATES							
OVERALL (a)	1/51 (2%)	0/55 (0%)	0/53 (0%)	1/53 (2%)	2/53 (4%)	0/52 (0%)	1/51 (2%)
POLY-3 RATE (b)	1/31.35	0/38.53	0/39.60	1/37.32	2/36.63	0/41.53	1/31.19
POLY-3 PERCENT (g)	3.2%	0.0%	0.0%	2.7%	5.5%	0.0%	3.2%
TERMINAL (d)	1/15 (7%)	0/25 (0%)	0/26 (0%)	1/22 (5%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	727 (T)	---	---	727 (T)	722	---	663
STATISTICAL TESTS							
LIFE TABLE	P=0.298	P=0.398N	P=0.390N	P=0.675N	P=0.536	P=0.415N	P=0.665
POLY 3	P=0.455	P=0.459N	P=0.454N	P=0.722N	P=0.554	P=0.445N	P=0.761
POLY 1.5	P=0.470	P=0.472N	P=0.469N	P=0.731N	P=0.538	P=0.463N	P=0.760N
POLY 6	P=0.443	P=0.439N	P=0.435N	P=0.712N	P=0.572	P=0.424N	P=0.750
LOGISTIC REGRESSION	P=0.392	(e)	(e)	P=0.675N	P=0.571	(e)	P=0.727
COCH-ARM / FISHERS	P=0.483	P=0.481N	P=0.490N	P=0.743N	P=0.515	P=0.495N	P=0.752N
ORDER RESTRICTED	P=0.512	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
				Females			
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma							
TUMOR RATES							
OVERALL (a)	15/51 (29%)	18/54 (33%)	20/53 (38%)	16/53 (30%)	22/53 (42%)	14/53 (26%)	6/53 (11%)
POLY-3 RATE (b)	15/32.57	18/41.27	20/43.98	16/40.27	22/39.95	14/43.88	6/32.96
POLY-3 PERCENT (g)	46.1%	43.6%	45.5%	39.7%	55.1%	31.9%	18.2%
TERMINAL (d)	9/15 (60%)	8/25 (32%)	10/26 (39%)	8/22 (36%)	10/16 (63%)	7/23 (30%)	1/7 (14%)
FIRST INCIDENCE	603	434	328	487	531	588	607
STATISTICAL TESTS							
LIFE TABLE	P=0.118N	P=0.271N	P=0.362N	P=0.280N	P=0.261	P=0.082N	P=0.214N
POLY 3	P=0.003N**	P=0.511N	P=0.574N	P=0.377N	P=0.289	P=0.150N	P=0.011N*
POLY 1.5	P=0.002N**	P=0.561	P=0.473	P=0.447N	P=0.221	P=0.234N	P=0.011N*
POLY 6	P=0.009N**	P=0.356N	P=0.424N	P=0.313N	P=0.372	P=0.087N	P=0.015N*
LOGISTIC REGRESSION	P=0.002N**	P=0.566N	P=0.483	P=0.397N	P=0.298	P=0.100N	P=0.028N*
COCH-ARM / FISHERS	P=0.002N**	P=0.412	P=0.245	P=0.551	P=0.139	P=0.451N	P=0.019N*
ORDER RESTRICTED	P=0.019N*	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	Females 100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
Pituitary Gland: Pars Distalis or Unspecified Site							
Carcinoma or Adenoma							
TUMOR RATES							
OVERALL (a)	15/51 (29%)	18/54 (33%)	20/53 (38%)	17/53 (32%)	22/53 (42%)	15/53 (28%)	6/53 (11%)
POLY-3 RATE (b)	15/32.57	18/41.27	20/43.98	17/40.27	22/39.95	15/43.88	6/32.96
POLY-3 PERCENT (g)	46.1%	43.6%	45.5%	42.2%	55.1%	34.2%	18.2%
TERMINAL (d)	9/15 (60%)	8/25 (32%)	10/26 (39%)	9/22 (41%)	10/16 (63%)	8/23 (35%)	1/7 (14%)
FIRST INCIDENCE	603	434	328	487	531	588	607
STATISTICAL TESTS							
LIFE TABLE	P=0.138N	P=0.271N	P=0.362N	P=0.340N	P=0.261	P=0.111N	P=0.214N
POLY 3	P=0.004N**	P=0.511N	P=0.574N	P=0.463N	P=0.289	P=0.205N	P=0.011N*
POLY 1.5	P=0.002N**	P=0.561	P=0.473	P=0.532N	P=0.221	P=0.304N	P=0.011N*
POLY 6	P=0.013N*	P=0.356N	P=0.424N	P=0.398N	P=0.372	P=0.125N	P=0.015N*
LOGISTIC REGRESSION	P=0.002N**	P=0.566N	P=0.483	P=0.478N	P=0.298	P=0.135N	P=0.028N*
COCH-ARM / FISHERS	P=0.002N**	P=0.412	P=0.245	P=0.468	P=0.139	P=0.536N	P=0.019N*
ORDER RESTRICTED	P=0.017N*	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	Females 100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
Pituitary Gland: Pars Intermedia							
Adenoma							
TUMOR RATES							
OVERALL (a)	1/51 (2%)	2/54 (4%)	1/53 (2%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	1/31.44	2/37.71	1/40.51	0/37.32	0/36.61	0/42.13	0/31.91
POLY-3 PERCENT (g)	3.2%	5.3%	2.5%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	0/15 (0%)	2/25 (8%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	554	727 (T)	328	---	---	---	---
STATISTICAL TESTS							
LIFE TABLE	P=0.114N	P=0.635	P=0.727N	P=0.463N	P=0.463N	P=0.435N	P=0.468N
POLY 3	P=0.080N	P=0.563	P=0.702N	P=0.466N	P=0.470N	P=0.442N	P=0.497N
POLY 1.5	P=0.088N	P=0.545	P=0.719N	P=0.472N	P=0.477N	P=0.458N	P=0.491N
POLY 6	P=0.076N	P=0.591	P=0.682N	P=0.462N	P=0.464N	P=0.426N	P=0.517N
LOGISTIC REGRESSION	P=0.101N	P=0.566	P=0.690	P=0.515N	P=0.502N	P=0.537N	P=0.494N
COCH-ARM / FISHERS	P=0.099N	P=0.522	P=0.743N	P=0.490N	P=0.490N	P=0.490N	P=0.490N
ORDER RESTRICTED	P=0.174N	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
				Females			
Thyroid Gland: C-Cell Adenoma							
TUMOR RATES							
OVERALL (a)	15/52 (29%)	15/55 (27%)	15/52 (29%)	13/51 (25%)	12/52 (23%)	12/50 (24%)	9/48 (19%)
POLY-3 RATE (b)	15/33.48	15/41.22	15/42.66	13/39.21	12/38.97	12/42.47	9/33.10
POLY-3 PERCENT (g)	44.8%	36.4%	35.2%	33.2%	30.8%	28.3%	27.2%
TERMINAL (d)	8/15 (53%)	8/25 (32%)	7/26 (27%)	8/22 (36%)	3/16 (19%)	7/23 (30%)	1/7 (14%)
FIRST INCIDENCE	519	524	541	385	454	588	394
STATISTICAL TESTS							
LIFE TABLE	P=0.415N	P=0.138N	P=0.122N	P=0.124N	P=0.194N	P=0.039N*	P=0.430N
POLY 3	P=0.085N	P=0.304N	P=0.265N	P=0.211N	P=0.155N	P=0.101N	P=0.096N
POLY 1.5	P=0.085N	P=0.397N	P=0.377N	P=0.273N	P=0.215N	P=0.173N	P=0.115N
POLY 6	P=0.111N	P=0.196N	P=0.160N	P=0.168N	P=0.104N	P=0.053N	P=0.097N
LOGISTIC REGRESSION	P=0.097N	P=0.307N	P=0.295N	P=0.240N	P=0.192N	P=0.067N	P=0.141N
COCH-ARM / FISHERS	P=0.105N	P=0.513N	P=0.586N	P=0.436N	P=0.328N	P=0.371N	P=0.172N
ORDER RESTRICTED	P=0.129N	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
				Females			
Thyroid Gland: C-Cell Carcinoma							
TUMOR RATES							
OVERALL (a)	0/52 (0%)	1/55 (2%)	2/52 (4%)	0/51 (0%)	0/52 (0%)	2/50 (4%)	0/48 (0%)
POLY-3 RATE (b)	0/31.37	1/38.53	2/39.64	0/36.51	0/35.79	2/41.02	0/29.95
POLY-3 PERCENT (g)	0.0%	2.6%	5.1%	0.0%	0.0%	4.9%	0.0%
TERMINAL (d)	0/15 (0%)	1/25 (4%)	1/26 (4%)	0/22 (0%)	0/16 (0%)	2/23 (9%)	0/7 (0%)
FIRST INCIDENCE	---	727 (T)	709	---	---	727 (T)	---
STATISTICAL TESTS							
LIFE TABLE	P=0.561	P=0.602	P=0.368	(e)	(e)	P=0.336	(e)
POLY 3	P=0.541N	P=0.541	P=0.292	(e)	(e)	P=0.302	(e)
POLY 1.5	P=0.536N	P=0.527	P=0.272	(e)	(e)	P=0.275	(e)
POLY 6	P=0.585N	P=0.561	P=0.318	(e)	(e)	P=0.333	(e)
LOGISTIC REGRESSION	P=0.620	P=0.602	P=0.341	(e)	(e)	P=0.336	(e)
COCH-ARM / FISHERS	P=0.539N	P=0.514	P=0.248	(e)	(e)	P=0.238	(e)
ORDER RESTRICTED	P=0.438	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Thyroid Gland: C-Cell Carcinoma or Adenoma							
TUMOR RATES							
OVERALL (a)	15/52 (29%)	16/55 (29%)	17/52 (33%)	13/51 (25%)	12/52 (23%)	14/50 (28%)	9/48 (19%)
POLY-3 RATE (b)	15/33.48	16/41.22	17/42.73	13/39.21	12/38.97	14/42.47	9/33.10
POLY-3 PERCENT (g)	44.8%	38.8%	39.8%	33.2%	30.8%	33.0%	27.2%
TERMINAL (d)	8/15 (53%)	9/25 (36%)	8/26 (31%)	8/22 (36%)	3/16 (19%)	9/23 (39%)	1/7 (14%)
FIRST INCIDENCE	519	524	541	385	454	588	394
STATISTICAL TESTS							
LIFE TABLE	P=0.437N	P=0.176N	P=0.200N	P=0.124N	P=0.194N	P=0.081N	P=0.430N
POLY 3	P=0.080N	P=0.385N	P=0.417N	P=0.211N	P=0.155N	P=0.204N	P=0.096N
POLY 1.5	P=0.079N	P=0.482N	P=0.543N	P=0.273N	P=0.215N	P=0.311N	P=0.115N
POLY 6	P=0.107N	P=0.261N	P=0.278N	P=0.168N	P=0.104N	P=0.120N	P=0.097N
LOGISTIC REGRESSION	P=0.091N	P=0.378N	P=0.436N	P=0.240N	P=0.192N	P=0.129N	P=0.141N
COCH-ARM / FISHERS	P=0.099N	P=0.574	P=0.416	P=0.436N	P=0.328N	P=0.550N	P=0.172N
ORDER RESTRICTED	P=0.133N	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Uterus Carcinoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	3/55 (5%)	1/53 (2%)	1/53 (2%)	0/53 (0%)	1/53 (2%)	0/53 (0%)
POLY-3 RATE (b)	0/31.38	3/38.64	1/39.86	1/37.32	0/36.61	1/42.13	0/31.91
POLY-3 PERCENT (g)	0.0%	7.8%	2.5%	2.7%	0.0%	2.4%	0.0%
TERMINAL (d)	0/15 (0%)	2/25 (8%)	0/26 (0%)	1/22 (5%)	0/16 (0%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	---	700	659	727 (T)	---	727 (T)	---
STATISTICAL TESTS							
LIFE TABLE	P=0.295N	P=0.228	P=0.568	P=0.576	(e)	P=0.585	(e)
POLY 3	P=0.170N	P=0.159	P=0.547	P=0.534	(e)	P=0.558	(e)
POLY 1.5	P=0.178N	P=0.144	P=0.531	P=0.525	(e)	P=0.538	(e)
POLY 6	P=0.177N	P=0.183	P=0.567	P=0.543	(e)	P=0.578	(e)
LOGISTIC REGRESSION	P=0.225N	P=0.206	P=0.535	P=0.576	(e)	P=0.585	(e)
COCH-ARM / FISHERS	P=0.193N	P=0.129	P=0.500	P=0.500	(e)	P=0.500	(e)
ORDER RESTRICTED	P=0.268N	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Uterus Polyp Stromal							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	4/53 (8%)	5/55 (9%)	7/53 (13%)	3/53 (6%)	8/53 (15%)	5/53 (9%)	4/53 (8%)
POLY-3 RATE (b)	4/31.79	5/39.02	7/40.14	3/37.58	8/37.70	5/42.23	4/32.95
POLY-3 PERCENT (g)	12.6%	12.8%	17.4%	8.0%	21.2%	11.8%	12.1%
TERMINAL (d)	2/15 (13%)	2/25 (8%)	4/26 (15%)	2/22 (9%)	5/16 (31%)	4/23 (17%)	1/7 (14%)
FIRST INCIDENCE	660	630	652	658	541	700	621
STATISTICAL TESTS							
LIFE TABLE	P=0.238	P=0.479N	P=0.591	P=0.328N	P=0.250	P=0.491N	P=0.440
POLY 3	P=0.444N	P=0.628	P=0.407	P=0.408N	P=0.263	P=0.601N	P=0.628N
POLY 1.5	P=0.431N	P=0.584	P=0.353	P=0.432N	P=0.230	P=0.617	P=0.623N
POLY 6	P=0.498N	P=0.591N	P=0.474	P=0.387N	P=0.297	P=0.543N	P=0.641
LOGISTIC REGRESSION	P=0.548	P=0.585N	P=0.497	P=0.369N	P=0.281	P=0.479N	P=0.613
COCH-ARM / FISHERS	P=0.441N	P=0.524	P=0.263	P=0.500N	P=0.179	P=0.500	P=0.642N
ORDER RESTRICTED	P=0.712N	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Uterus Sarcoma Stromal							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	0/55 (0%)	0/53 (0%)	2/53 (4%)	2/53 (4%)	2/53 (4%)	0/53 (0%)
POLY-3 RATE (b)	0/31.38	0/38.53	0/39.60	2/37.58	2/36.68	2/42.18	0/31.91
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	5.3%	5.5%	4.7%	0.0%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	1/22 (5%)	1/16 (6%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	658	709	714	---
STATISTICAL TESTS							
LIFE TABLE	P=0.300	(e)	(e)	P=0.322	P=0.277	P=0.361	(e)
POLY 3	P=0.410	(e)	(e)	P=0.279	P=0.273	P=0.308	(e)
POLY 1.5	P=0.462	(e)	(e)	P=0.267	P=0.260	P=0.283	(e)
POLY 6	P=0.329	(e)	(e)	P=0.291	P=0.285	P=0.337	(e)
LOGISTIC REGRESSION	P=0.416	(e)	(e)	P=0.285	P=0.287	P=0.361	(e)
COCH-ARM / FISHERS	P=0.507	(e)	(e)	P=0.248	P=0.248	P=0.248	(e)
ORDER RESTRICTED	P=0.297	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Uterus Sarcoma Stromal or Polyp Stromal							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	4/53 (8%)	5/55 (9%)	7/53 (13%)	5/53 (9%)	10/53 (19%)	7/53 (13%)	4/53 (8%)
POLY-3 RATE (b)	4/31.79	5/39.02	7/40.14	5/37.84	10/37.77	7/42.29	4/32.95
POLY-3 PERCENT (g)	12.6%	12.8%	17.4%	13.2%	26.5%	16.6%	12.1%
TERMINAL (d)	2/15 (13%)	2/25 (8%)	4/26 (15%)	3/22 (14%)	6/16 (38%)	5/23 (22%)	1/7 (14%)
FIRST INCIDENCE	660	630	652	658	541	700	621
STATISTICAL TESTS							
LIFE TABLE	P=0.158	P=0.479N	P=0.591	P=0.571N	P=0.123	P=0.575	P=0.440
POLY 3	P=0.516N	P=0.628	P=0.407	P=0.610	P=0.124	P=0.443	P=0.628N
POLY 1.5	P=0.488N	P=0.584	P=0.353	P=0.580	P=0.103	P=0.379	P=0.623N
POLY 6	P=0.470	P=0.591N	P=0.474	P=0.638	P=0.146	P=0.511	P=0.641
LOGISTIC REGRESSION	P=0.469	P=0.585N	P=0.497	P=0.636N	P=0.141	P=0.592	P=0.613
COCH-ARM / FISHERS	P=0.487N	P=0.524	P=0.263	P=0.500	P=0.075	P=0.263	P=0.642N
ORDER RESTRICTED	P=0.505	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Uterus Schwannoma Malignant							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	0/55 (0%)	0/53 (0%)	0/53 (0%)	1/53 (2%)	2/53 (4%)	0/53 (0%)
POLY-3 RATE (b)	0/31.38	0/38.53	0/39.60	0/37.32	1/36.86	2/42.23	0/31.91
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	2.7%	4.7%	0.0%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	658	700	---
STATISTICAL TESTS							
LIFE TABLE	P=0.204	(e)	(e)	(e)	P=0.562	P=0.358	(e)
POLY 3	P=0.213	(e)	(e)	(e)	P=0.532	P=0.309	(e)
POLY 1.5	P=0.264	(e)	(e)	(e)	P=0.521	P=0.283	(e)
POLY 6	P=0.151	(e)	(e)	(e)	P=0.543	P=0.337	(e)
LOGISTIC REGRESSION	P=0.286	(e)	(e)	(e)	P=0.525	P=0.350	(e)
COCH-ARM / FISHERS	P=0.327	(e)	(e)	(e)	P=0.500	P=0.248	(e)
ORDER RESTRICTED	P=0.326	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
All Organs Hemangiosarcoma							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	2/53 (4%)	0/55 (0%)	0/53 (0%)	1/53 (2%)	0/53 (0%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	2/31.60	0/38.53	0/39.60	1/37.32	0/36.61	0/42.13	0/31.91
POLY-3 PERCENT (g)	6.3%	0.0%	0.0%	2.7%	0.0%	0.0%	0.0%
TERMINAL (d)	1/15 (7%)	0/25 (0%)	0/26 (0%)	1/22 (5%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	671	---	---	727 (T)	---	---	---
STATISTICAL TESTS							
LIFE TABLE	P=0.226N	P=0.139N	P=0.138N	P=0.390N	P=0.208N	P=0.138N	P=0.352N
POLY 3	P=0.181N	P=0.195N	P=0.190N	P=0.442N	P=0.205N	P=0.179N	P=0.233N
POLY 1.5	P=0.182N	P=0.208N	P=0.206N	P=0.457N	P=0.216N	P=0.197N	P=0.230N
POLY 6	P=0.198N	P=0.177N	P=0.174N	P=0.429N	P=0.196N	P=0.163N	P=0.251N
LOGISTIC REGRESSION	P=0.190N	P=0.168N	P=0.164N	P=0.409N	P=0.191N	P=0.151N	P=0.277N
COCH-ARM / FISHERS	P=0.182N	P=0.238N	P=0.248N	P=0.500N	P=0.248N	P=0.248N	P=0.248N
ORDER RESTRICTED	P=0.020N*	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
All Organs Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	2/55 (4%)	0/53 (0%)	2/53 (4%)	1/53 (2%)	1/53 (2%)	2/53 (4%)
POLY-3 RATE (b)	0/31.38	2/40.04	0/39.60	2/37.84	1/37.22	1/42.64	2/32.66
POLY-3 PERCENT (g)	0.0%	5.0%	0.0%	5.3%	2.7%	2.4%	6.1%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	0/22 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	82	---	658	531	573	611
STATISTICAL TESTS							
LIFE TABLE	P=0.238	P=0.265	(e)	P=0.316	P=0.534	P=0.566	P=0.230
POLY 3	P=0.264	P=0.294	(e)	P=0.280	P=0.534	P=0.560	P=0.244
POLY 1.5	P=0.268	P=0.275	(e)	P=0.268	P=0.522	P=0.540	P=0.246
POLY 6	P=0.264	P=0.324	(e)	P=0.295	P=0.546	P=0.581	P=0.232
LOGISTIC REGRESSION	P=0.265	P=0.195	(e)	P=0.269	P=0.484	P=0.470	P=0.241
COCH-ARM / FISHERS	P=0.264	P=0.257	(e)	P=0.248	P=0.500	P=0.500	P=0.248
ORDER RESTRICTED	P=0.168	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
All Organs Benign Tumors							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	45/53 (85%)	45/55 (82%)	48/53 (91%)	45/53 (85%)	46/53 (87%)	45/53 (85%)	42/53 (79%)
POLY-3 RATE (b)	45/45.97	45/47.51	48/51.17	45/48.55	46/49.09	45/47.95	42/45.75
POLY-3 PERCENT (g)	97.9%	94.7%	93.8%	92.7%	93.7%	93.8%	91.8%
TERMINAL (d)	15/15 (100%)	24/25 (96%)	23/26 (89%)	21/22 (96%)	14/16 (88%)	23/23 (100%)	7/7 (100%)
FIRST INCIDENCE	309	356	188	385	247	440	258
STATISTICAL TESTS							
LIFE TABLE	P=0.020 *	P=0.016N*	P=0.032N*	P=0.068N	P=0.258N	P=0.007N**	P=0.258
POLY 3	P=0.207N	P=0.377N	P=0.296N	P=0.180N	P=0.285N	P=0.270N	P=0.135N
POLY 1.5	P=0.153N	P=0.381N	P=0.480N	P=0.234N	P=0.424N	P=0.302N	P=0.152N
POLY 6	P=0.395N	P=0.336N	P=0.201N	P=0.260N	P=0.218N	P=0.362N	P=0.188N
LOGISTIC REGRESSION	P=0.100N	P=0.158N	P=0.613N	P=0.117N	P=0.454N	P=0.020N*	P=0.100N
COCH-ARM / FISHERS	P=0.191N	P=0.432N	P=0.278	P=0.607N	P=0.500	P=0.607N	P=0.307N
ORDER RESTRICTED	P=0.143N	(e)	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
All Organs Malignant Tumors							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	13/53 (25%)	19/55 (35%)	18/53 (34%)	15/53 (28%)	16/53 (30%)	23/53 (43%)	33/53 (62%)
POLY-3 RATE (b)	13/35.14	19/45.38	18/44.03	15/40.97	16/40.41	23/46.99	33/43.01
POLY-3 PERCENT (g)	37.0%	41.9%	40.9%	36.6%	39.6%	48.9%	76.7%
TERMINAL (d)	5/15 (33%)	6/25 (24%)	8/26 (31%)	8/22 (36%)	6/16 (38%)	10/23 (44%)	6/7 (86%)
FIRST INCIDENCE	176	82	236	448	40	185	72
STATISTICAL TESTS							
LIFE TABLE	P<0.001 **	P=0.555	P=0.483N	P=0.425N	P=0.509	P=0.370	P<0.001 **
POLY 3	P<0.001 **	P=0.414	P=0.451	P=0.583N	P=0.502	P=0.192	P<0.001 **
POLY 1.5	P<0.001 **	P=0.312	P=0.343	P=0.543	P=0.433	P=0.109	P<0.001 **
POLY 6	P<0.001 **	P=0.561	P=0.592	P=0.520N	P=0.584	P=0.323	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	P=0.162	P=0.244	P=0.500	P=0.385	P=0.049 *	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	P=0.177	P=0.197	P=0.413	P=0.332	P=0.032 *	P<0.001 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
All Organs Malignant and Benign Tumors							
TUMOR RATES	#	#	#	#	#	#	#
OVERALL (a)	49/53 (92%)	51/55 (93%)	51/53 (96%)	47/53 (89%)	49/53 (92%)	50/53 (94%)	49/53 (92%)
POLY-3 RATE (b)	49/49.21	51/52.35	51/52.14	47/49.77	49/50.28	50/51.09	49/50.22
POLY-3 PERCENT (g)	99.6%	97.4%	97.8%	94.4%	97.5%	97.9%	97.6%
TERMINAL (d)	15/15 (100%)	24/25 (96%)	25/26 (96%)	21/22 (96%)	15/16 (94%)	23/23 (100%)	7/7 (100%)
FIRST INCIDENCE	176	82	188	385	40	185	72
STATISTICAL TESTS							
LIFE TABLE	P=0.006 **	P=0.036N*	P=0.021N*	P=0.043N*	P=0.215N	P=0.012N*	P=0.175
POLY 3	P=0.579N	P=0.466N	P=0.543N	P=0.125N	P=0.481N	P=0.576N	P=0.504N
POLY 1.5	P=0.521N	P=0.452N	P=0.654N	P=0.134N	P=0.494N	P=0.541N	P=0.458N
POLY 6	P=0.534	P=0.507N	P=0.515N	P=0.229N	P=0.499N	P=0.896N	P=0.750N
LOGISTIC REGRESSION	P=0.528N	P=0.547N	P=0.661	P=0.066N	P=0.470N	P=0.299N	P=0.541N
COCH-ARM / FISHERS	P=0.542	P=0.621	P=0.339	P=0.371N	P=0.642N	P=0.500	P=0.642N
ORDER RESTRICTED	P=0.279N	(e)	(e)	(e)	(e)	(e)	(e)

(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).

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

FINAL #2 RATS CTRL VS GRPS 3, 4, & 5

REASONS FOR REMOVAL:
25022 Accidently Killed
25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:

INCLUDE 001	0	NG/KG
INCLUDE 003	30	NG/KG
INCLUDE 004	100	NG/KG
INCLUDE 005	175	NG/KG

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 01
TEST TYPE: CHRONIC
CONT: N01-ES-75411
PATHOLOGIST: MISSING
Rats(SPRAGUE-DAWLEY)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 11:23:38

NTP C#: 96007D
CAS: 57465-28-8

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
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Ovary
Pancreas
Parathyroid Gland
Pituitary Gland
Thyroid Gland

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 01
TEST TYPE: CHRONIC
CONT: N01-ES-75411
PATHOLOGIST: MISSING

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 11:23:38

NTP C#: 96007D
CAS: 57465-28-8

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TOXIC EQUIVALENCY FACTOR EVALUATION (

Female Rats

Organ	Morphology
Adrenal Medulla	Pheochromocytoma Benign
	Pheochromocytoma: Benign, Complex, Malignant, NOS
Brain	Astrocytoma Malignant
	Oligodendroglioma, Glioma, or Astrocytoma
Mammary Gland	Fibroadenoma
	Fibroma, Fibroadenoma or Adenoma
	Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Uterus	Sarcoma Stromal
All Organs	Benign Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Adrenal Medulla Pheochromocytoma Benign				
TUMOR RATES				
OVERALL (a)	8/52 (15%)	3/55 (5%)	4/53 (8%)	2/53 (4%)
POLY-3 RATE (b)	8/33.26	3/38.95	4/40.27	2/37.58
POLY-3 PERCENT (g)	24.1%	7.7%	9.9%	5.3%
TERMINAL (d)	3/15 (20%)	2/25 (8%)	2/26 (8%)	1/22 (5%)
FIRST INCIDENCE	531	607	586	660
STATISTICAL TESTS				
LIFE TABLE	P=0.032N*	P=0.028N*	P=0.050N	P=0.020N*
POLY 3	P=0.045N*	P=0.052N	P=0.093N	P=0.025N*
POLY 1.5	P=0.045N*	P=0.064N	P=0.115N	P=0.028N*
POLY 6	P=0.050N	P=0.039N*	P=0.072N	P=0.022N*
LOGISTIC REGRESSION	P=0.038N*	P=0.052N	P=0.097N	P=0.025N*
COCH-ARM / FISHERS	P=0.059N	P=0.084N	P=0.170N	P=0.043N*
ORDER RESTRICTED	P=0.010N*	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Adrenal Medulla Pheochromocytoma: Benign, Complex, Malignant, NOS				
TUMOR RATES				
OVERALL (a)	8/52 (15%)	3/55 (5%)	5/53 (9%)	3/53 (6%)
POLY-3 RATE (b)	8/33.26	3/38.95	5/40.34	3/38.25
POLY-3 PERCENT (g)	24.1%	7.7%	12.4%	7.8%
TERMINAL (d)	3/15 (20%)	2/25 (8%)	2/26 (8%)	1/22 (5%)
FIRST INCIDENCE	531	607	586	500
STATISTICAL TESTS				
LIFE TABLE	P=0.091N	P=0.028N*	P=0.086N	P=0.048N*
POLY 3	P=0.115N	P=0.052N	P=0.158N	P=0.055N
POLY 1.5	P=0.117N	P=0.064N	P=0.191N	P=0.064N
POLY 6	P=0.122N	P=0.039N*	P=0.126N	P=0.050N
LOGISTIC REGRESSION	P=0.108N	P=0.052N	P=0.158N	P=0.064N
COCH-ARM / FISHERS	P=0.146N	P=0.084N	P=0.265N	P=0.095N
ORDER RESTRICTED	P=0.029N*	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Brain				
Astrocytoma Malignant				
TUMOR RATES				
OVERALL (a)	2/53 (4%)	0/55 (0%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	2/31.82	0/38.53	0/39.60	0/37.32
POLY-3 PERCENT (g)	6.3%	0.0%	0.0%	0.0%
TERMINAL (d)	1/15 (7%)	0/25 (0%)	0/26 (0%)	0/22 (0%)
FIRST INCIDENCE	600	---	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.091N	P=0.165N	P=0.156N	P=0.183N
POLY 3	P=0.125N	P=0.196N	P=0.191N	P=0.202N
POLY 1.5	P=0.119N	P=0.209N	P=0.206N	P=0.211N
POLY 6	P=0.138N	P=0.179N	P=0.176N	P=0.196N
LOGISTIC REGRESSION	P=0.101N	P=0.197N	P=0.194N	P=0.202N
COCH-ARM / FISHERS	P=0.115N	P=0.238N	P=0.248N	P=0.248N
ORDER RESTRICTED	P=0.019N*	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Brain				
Oligodendroglioma, Glioma, or Astrocytoma				
TUMOR RATES				
OVERALL (a)	3/53 (6%)	0/55 (0%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	3/32.80	0/38.53	0/39.60	0/37.32
POLY-3 PERCENT (g)	9.2%	0.0%	0.0%	0.0%
TERMINAL (d)	1/15 (7%)	0/25 (0%)	0/26 (0%)	0/22 (0%)
FIRST INCIDENCE	201	---	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.041N*	P=0.082N	P=0.079N	P=0.093N
POLY 3	P=0.053N	P=0.091N	P=0.088N	P=0.096N
POLY 1.5	P=0.050N	P=0.100N	P=0.098N	P=0.101N
POLY 6	P=0.060N	P=0.079N	P=0.077N	P=0.091N
LOGISTIC REGRESSION	P=0.065N	P=0.128N	P=0.156N	P=0.155N
COCH-ARM / FISHERS	P=0.051N	P=0.115N	P=0.121N	P=0.121N
ORDER RESTRICTED	P=0.005N**	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Heart				
Schwannoma Malignant				
TUMOR RATES				
OVERALL (a)	0/52 (0%)	1/54 (2%)	2/53 (4%)	0/53 (0%)
POLY-3 RATE (b)	0/31.37	1/37.81	2/40.29	0/37.32
POLY-3 PERCENT (g)	0.0%	2.6%	5.0%	0.0%
TERMINAL (d)	0/15 (0%)	0/24 (0%)	0/26 (0%)	0/22 (0%)
FIRST INCIDENCE	---	652	602	---
STATISTICAL TESTS				
LIFE TABLE	P=0.601N	P=0.578	P=0.312	(e)
POLY 3	P=0.579N	P=0.537	P=0.296	(e)
POLY 1.5	P=0.591N	P=0.523	P=0.275	(e)
POLY 6	P=0.577N	P=0.558	P=0.325	(e)
LOGISTIC REGRESSION	P=0.616N	P=0.526	P=0.253	(e)
COCH-ARM / FISHERS	P=0.624	P=0.509	P=0.252	(e)
ORDER RESTRICTED	P=0.352N	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Intestine Small: Jejunum				
Leiomyosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/53 (0%)	0/55 (0%)	2/53 (4%)	0/53 (0%)
POLY-3 RATE (b)	0/31.38	0/38.53	2/39.60	0/37.32
POLY-3 PERCENT (g)	0.0%	0.0%	5.1%	0.0%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	2/26 (8%)	0/22 (0%)
FIRST INCIDENCE	---	---	727 (T)	---
STATISTICAL TESTS				
LIFE TABLE	P=0.505	(e)	P=0.365	(e)
POLY 3	P=0.499	(e)	P=0.292	(e)
POLY 1.5	P=0.495	(e)	P=0.272	(e)
POLY 6	P=0.493	(e)	P=0.317	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.365	(e)
COCH-ARM / FISHERS	P=0.454	(e)	P=0.248	(e)
ORDER RESTRICTED	P=0.294	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
		Females		
Intestine Small: Site Unspecified Leiomyosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/53 (0%)	0/55 (0%)	2/53 (4%)	0/53 (0%)
POLY-3 RATE (b)	0/31.38	0/38.53	2/39.60	0/37.32
POLY-3 PERCENT (g)	0.0%	0.0%	5.1%	0.0%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	2/26 (8%)	0/22 (0%)
FIRST INCIDENCE	---	---	727 (T)	---
STATISTICAL TESTS				
LIFE TABLE	P=0.505	(e)	P=0.365	(e)
POLY 3	P=0.499	(e)	P=0.292	(e)
POLY 1.5	P=0.495	(e)	P=0.272	(e)
POLY 6	P=0.493	(e)	P=0.317	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.365	(e)
COCH-ARM / FISHERS	P=0.454	(e)	P=0.248	(e)
ORDER RESTRICTED	P=0.294	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
		Females		
Islets, Pancreatic Adenoma				
TUMOR RATES				
OVERALL (a)	0/52 (0%)	2/54 (4%)	0/53 (0%)	1/53 (2%)
POLY-3 RATE (b)	0/31.36	2/38.32	0/39.60	1/37.32
POLY-3 PERCENT (g)	0.0%	5.2%	0.0%	2.7%
TERMINAL (d)	0/15 (0%)	1/25 (4%)	0/26 (0%)	1/22 (5%)
FIRST INCIDENCE	---	652	---	727 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.599N	P=0.343	(e)	P=0.576
POLY 3	P=0.589N	P=0.283	(e)	P=0.535
POLY 1.5	P=0.610N	P=0.265	(e)	P=0.526
POLY 6	P=0.568N	P=0.312	(e)	P=0.543
LOGISTIC REGRESSION	P=0.617N	P=0.292	(e)	P=0.576
COCH-ARM / FISHERS	P=0.608	P=0.257	(e)	P=0.505
ORDER RESTRICTED	P=0.360	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Islets, Pancreatic				
Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	0/52 (0%)	2/54 (4%)	1/53 (2%)	1/53 (2%)
POLY-3 RATE (b)	0/31.36	2/38.32	1/40.08	1/37.32
POLY-3 PERCENT (g)	0.0%	5.2%	2.5%	2.7%
TERMINAL (d)	0/15 (0%)	1/25 (4%)	0/26 (0%)	1/22 (5%)
FIRST INCIDENCE	---	652	586	727 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.581	P=0.343	P=0.551	P=0.576
POLY 3	P=0.594	P=0.283	P=0.548	P=0.535
POLY 1.5	P=0.575	P=0.265	P=0.532	P=0.526
POLY 6	P=0.616	P=0.312	P=0.568	P=0.543
LOGISTIC REGRESSION	P=0.557	P=0.292	P=0.494	P=0.576
COCH-ARM / FISHERS	P=0.524	P=0.257	P=0.505	P=0.505
ORDER RESTRICTED	P=0.318	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Kidney: Renal Tubule				
Nephroblastoma				
TUMOR RATES				
OVERALL (a)	1/53 (2%)	2/55 (4%)	1/53 (2%)	1/53 (2%)
POLY-3 RATE (b)	1/32.37	2/40.46	1/40.57	1/38.09
POLY-3 PERCENT (g)	3.1%	4.9%	2.5%	2.6%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	0/22 (0%)
FIRST INCIDENCE	176	223	236	448
STATISTICAL TESTS				
LIFE TABLE	P=0.456N	P=0.525	P=0.749N	P=0.741N
POLY 3	P=0.433N	P=0.577	P=0.708N	P=0.724N
POLY 1.5	P=0.446N	P=0.551	P=0.727N	P=0.735N
POLY 6	P=0.429N	P=0.611	P=0.685N	P=0.713N
LOGISTIC REGRESSION	P=0.368	P=0.422	P=0.497	P=0.581
COCH-ARM / FISHERS	P=0.482N	P=0.514	P=0.752N	P=0.752N
ORDER RESTRICTED	P=0.567N	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Liver				
Hepatocellular Adenoma				
TUMOR RATES				
OVERALL (a)	1/53 (2%)	2/55 (4%)	1/53 (2%)	0/53 (0%)
POLY-3 RATE (b)	1/31.38	2/38.81	1/40.03	0/37.32
POLY-3 PERCENT (g)	3.2%	5.2%	2.5%	0.0%
TERMINAL (d)	1/15 (7%)	1/25 (4%)	0/26 (0%)	0/22 (0%)
FIRST INCIDENCE	727 (T)	652	602	---
STATISTICAL TESTS				
LIFE TABLE	P=0.167N	P=0.661	P=0.664N	P=0.424N
POLY 3	P=0.175N	P=0.574	P=0.704N	P=0.465N
POLY 1.5	P=0.185N	P=0.548	P=0.725N	P=0.475N
POLY 6	P=0.171N	P=0.610	P=0.677N	P=0.457N
LOGISTIC REGRESSION	P=0.184N	P=0.616	P=0.723N	(e)
COCH-ARM / FISHERS	P=0.214N	P=0.514	P=0.752N	P=0.500N
ORDER RESTRICTED	P=0.237N	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Liver				
Hepatocellular Carcinoma or Hepatocellular Adenoma				
TUMOR RATES				
OVERALL (a)	1/53 (2%)	2/55 (4%)	1/53 (2%)	1/53 (2%)
POLY-3 RATE (b)	1/31.38	2/38.81	1/40.03	1/37.32
POLY-3 PERCENT (g)	3.2%	5.2%	2.5%	2.7%
TERMINAL (d)	1/15 (7%)	1/25 (4%)	0/26 (0%)	1/22 (5%)
FIRST INCIDENCE	727 (T)	652	602	727 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.411N	P=0.661	P=0.664N	P=0.675N
POLY 3	P=0.427N	P=0.574	P=0.704N	P=0.722N
POLY 1.5	P=0.441N	P=0.548	P=0.725N	P=0.732N
POLY 6	P=0.423N	P=0.610	P=0.677N	P=0.711N
LOGISTIC REGRESSION	P=0.435N	P=0.616	P=0.723N	P=0.675N
COCH-ARM / FISHERS	P=0.482N	P=0.514	P=0.752N	P=0.752N
ORDER RESTRICTED	P=0.559N	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Liver Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma				
TUMOR RATES				
OVERALL (a)	1/53 (2%)	2/55 (4%)	1/53 (2%)	1/53 (2%)
POLY-3 RATE (b)	1/31.38	2/38.81	1/40.03	1/37.32
POLY-3 PERCENT (g)	3.2%	5.2%	2.5%	2.7%
TERMINAL (d)	1/15 (7%)	1/25 (4%)	0/26 (0%)	1/22 (5%)
FIRST INCIDENCE	727 (T)	652	602	727 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.411N	P=0.661	P=0.664N	P=0.675N
POLY 3	P=0.427N	P=0.574	P=0.704N	P=0.722N
POLY 1.5	P=0.441N	P=0.548	P=0.725N	P=0.732N
POLY 6	P=0.423N	P=0.610	P=0.677N	P=0.711N
LOGISTIC REGRESSION	P=0.435N	P=0.616	P=0.723N	P=0.675N
COCH-ARM / FISHERS	P=0.482N	P=0.514	P=0.752N	P=0.752N
ORDER RESTRICTED	P=0.559N	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Mammary Gland Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/53 (4%)	0/55 (0%)	2/53 (4%)	0/53 (0%)
POLY-3 RATE (b)	2/31.38	0/38.53	2/40.21	0/37.32
POLY-3 PERCENT (g)	6.4%	0.0%	5.0%	0.0%
TERMINAL (d)	2/15 (13%)	0/25 (0%)	1/26 (4%)	0/22 (0%)
FIRST INCIDENCE	727 (T)	---	533	---
STATISTICAL TESTS				
LIFE TABLE	P=0.250N	P=0.134N	P=0.523N	P=0.157N
POLY 3	P=0.304N	P=0.193N	P=0.602N	P=0.200N
POLY 1.5	P=0.297N	P=0.208N	P=0.636N	P=0.210N
POLY 6	P=0.327N	P=0.174N	P=0.560N	P=0.190N
LOGISTIC REGRESSION	P=0.274N	(e)	P=0.608N	(e)
COCH-ARM / FISHERS	P=0.311N	P=0.238N	P=0.691N	P=0.248N
ORDER RESTRICTED	P=0.091N	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Mammary Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	6/53 (11%)	7/55 (13%)	9/53 (17%)	5/53 (9%)
POLY-3 RATE (b)	6/32.44	7/39.35	9/40.77	5/38.47
POLY-3 PERCENT (g)	18.5%	17.8%	22.1%	13.0%
TERMINAL (d)	3/15 (20%)	3/25 (12%)	6/26 (23%)	3/22 (14%)
FIRST INCIDENCE	400	580	533	496
STATISTICAL TESTS				
LIFE TABLE	P=0.302N	P=0.397N	P=0.557N	P=0.299N
POLY 3	P=0.348N	P=0.591N	P=0.466	P=0.379N
POLY 1.5	P=0.371N	P=0.598	P=0.399	P=0.413N
POLY 6	P=0.346N	P=0.514N	P=0.551	P=0.347N
LOGISTIC REGRESSION	P=0.362N	P=0.569N	P=0.474	P=0.397N
COCH-ARM / FISHERS	P=0.470N	P=0.529	P=0.289	P=0.500N
ORDER RESTRICTED	P=0.387N	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Mammary Gland Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	7/53 (13%)	7/55 (13%)	10/53 (19%)	5/53 (9%)
POLY-3 RATE (b)	7/32.44	7/39.35	10/40.77	5/38.47
POLY-3 PERCENT (g)	21.6%	17.8%	24.5%	13.0%
TERMINAL (d)	4/15 (27%)	3/25 (12%)	7/26 (27%)	3/22 (14%)
FIRST INCIDENCE	400	580	533	496
STATISTICAL TESTS				
LIFE TABLE	P=0.243N	P=0.270N	P=0.496N	P=0.191N
POLY 3	P=0.291N	P=0.459N	P=0.493	P=0.259N
POLY 1.5	P=0.313N	P=0.514N	P=0.419	P=0.292N
POLY 6	P=0.292N	P=0.376N	P=0.586	P=0.228N
LOGISTIC REGRESSION	P=0.298N	P=0.426N	P=0.522	P=0.271N
COCH-ARM / FISHERS	P=0.411N	P=0.583N	P=0.299	P=0.380N
ORDER RESTRICTED	P=0.297N	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Mammary Gland Fibroadenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	39/53 (74%)	31/55 (56%)	35/53 (66%)	38/53 (72%)
POLY-3 RATE (b)	39/45.19	31/45.30	35/47.68	38/47.78
POLY-3 PERCENT (g)	86.3%	68.4%	73.4%	79.5%
TERMINAL (d)	11/15 (73%)	18/25 (72%)	18/26 (69%)	16/22 (73%)
FIRST INCIDENCE	309	356	188	385
STATISTICAL TESTS				
LIFE TABLE	P=0.272N	P=0.003N**	P=0.010N*	P=0.095N
POLY 3	P=0.474N	P=0.029N*	P=0.085N	P=0.263N
POLY 1.5	P=0.496N	P=0.027N*	P=0.095N	P=0.274N
POLY 6	P=0.523N	P=0.033N*	P=0.101N	P=0.318N
LOGISTIC REGRESSION	P=0.512	P=0.015N*	P=0.127N	P=0.283N
COCH-ARM / FISHERS	P=0.333	P=0.047N*	P=0.263N	P=0.500N
ORDER RESTRICTED	P=0.099N	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Mammary Gland Fibroma, Fibroadenoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	40/53 (75%)	31/55 (56%)	36/53 (68%)	38/53 (72%)
POLY-3 RATE (b)	40/45.19	31/45.30	36/48.29	38/47.78
POLY-3 PERCENT (g)	88.5%	68.4%	74.6%	79.5%
TERMINAL (d)	12/15 (80%)	18/25 (72%)	18/26 (69%)	16/22 (73%)
FIRST INCIDENCE	309	356	188	385
STATISTICAL TESTS				
LIFE TABLE	P=0.243N	P=0.002N**	P=0.009N**	P=0.070N
POLY 3	P=0.400N	P=0.013N*	P=0.058N	P=0.165N
POLY 1.5	P=0.431N	P=0.013N*	P=0.074N	P=0.182N
POLY 6	P=0.439N	P=0.014N*	P=0.062N	P=0.203N
LOGISTIC REGRESSION	P=0.506N	P=0.008N**	P=0.118N	P=0.194N
COCH-ARM / FISHERS	P=0.373	P=0.029N*	P=0.259N	P=0.413N
ORDER RESTRICTED	P=0.057N	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	42/53 (79%)	36/55 (65%)	38/53 (72%)	39/53 (74%)
POLY-3 RATE (b)	42/46.17	36/46.12	38/48.57	39/48.24
POLY-3 PERCENT (g)	91.0%	78.1%	78.2%	80.8%
TERMINAL (d)	12/15 (80%)	19/25 (76%)	19/26 (73%)	16/22 (73%)
FIRST INCIDENCE	309	356	188	385
STATISTICAL TESTS				
LIFE TABLE	P=0.138N	P=0.005N**	P=0.007N**	P=0.054N
POLY 3	P=0.192N	P=0.064N	P=0.064N	P=0.114N
POLY 1.5	P=0.212N	P=0.056N	P=0.073N	P=0.122N
POLY 6	P=0.231N	P=0.072N	P=0.075N	P=0.149N
LOGISTIC REGRESSION	P=0.274N	P=0.023N*	P=0.104N	P=0.134N
COCH-ARM / FISHERS	P=0.492N	P=0.083N	P=0.249N	P=0.324N
ORDER RESTRICTED	P=0.083N	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma				
TUMOR RATES				
OVERALL (a)	15/51 (29%)	18/54 (33%)	20/53 (38%)	16/53 (30%)
POLY-3 RATE (b)	15/32.57	18/41.27	20/43.98	16/40.27
POLY-3 PERCENT (g)	46.1%	43.6%	45.5%	39.7%
TERMINAL (d)	9/15 (60%)	8/25 (32%)	10/26 (39%)	8/22 (36%)
FIRST INCIDENCE	603	434	328	487
STATISTICAL TESTS				
LIFE TABLE	P=0.344N	P=0.271N	P=0.362N	P=0.280N
POLY 3	P=0.352N	P=0.511N	P=0.574N	P=0.377N
POLY 1.5	P=0.391N	P=0.561	P=0.473	P=0.447N
POLY 6	P=0.358N	P=0.356N	P=0.424N	P=0.313N
LOGISTIC REGRESSION	P=0.405N	P=0.566N	P=0.483	P=0.397N
COCH-ARM / FISHERS	P=0.494	P=0.412	P=0.245	P=0.551
ORDER RESTRICTED	P=0.470N	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Pituitary Gland: Pars Distalis or Unspecified Site				
Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	15/51 (29%)	18/54 (33%)	20/53 (38%)	17/53 (32%)
POLY-3 RATE (b)	15/32.57	18/41.27	20/43.98	17/40.27
POLY-3 PERCENT (g)	46.1%	43.6%	45.5%	42.2%
TERMINAL (d)	9/15 (60%)	8/25 (32%)	10/26 (39%)	9/22 (41%)
FIRST INCIDENCE	603	434	328	487
STATISTICAL TESTS				
LIFE TABLE	P=0.417N	P=0.271N	P=0.362N	P=0.340N
POLY 3	P=0.443N	P=0.511N	P=0.574N	P=0.463N
POLY 1.5	P=0.480N	P=0.561	P=0.473	P=0.532N
POLY 6	P=0.453N	P=0.356N	P=0.424N	P=0.398N
LOGISTIC REGRESSION	P=0.489N	P=0.566N	P=0.483	P=0.478N
COCH-ARM / FISHERS	P=0.410	P=0.412	P=0.245	P=0.468
ORDER RESTRICTED	P=0.585N	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Pituitary Gland: Pars Intermedia				
Adenoma				
TUMOR RATES				
OVERALL (a)	1/51 (2%)	2/54 (4%)	1/53 (2%)	0/53 (0%)
POLY-3 RATE (b)	1/31.44	2/37.71	1/40.51	0/37.32
POLY-3 PERCENT (g)	3.2%	5.3%	2.5%	0.0%
TERMINAL (d)	0/15 (0%)	2/25 (8%)	0/26 (0%)	0/22 (0%)
FIRST INCIDENCE	554	727 (T)	328	---
STATISTICAL TESTS				
LIFE TABLE	P=0.171N	P=0.635	P=0.727N	P=0.463N
POLY 3	P=0.174N	P=0.563	P=0.702N	P=0.466N
POLY 1.5	P=0.181N	P=0.545	P=0.719N	P=0.472N
POLY 6	P=0.172N	P=0.591	P=0.682N	P=0.462N
LOGISTIC REGRESSION	P=0.217N	P=0.566	P=0.690	P=0.515N
COCH-ARM / FISHERS	P=0.206N	P=0.522	P=0.743N	P=0.490N
ORDER RESTRICTED	P=0.230N	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Thyroid Gland: C-Cell Adenoma				
TUMOR RATES				
OVERALL (a)	15/52 (29%)	15/55 (27%)	15/52 (29%)	13/51 (25%)
POLY-3 RATE (b)	15/33.48	15/41.22	15/42.66	13/39.21
POLY-3 PERCENT (g)	44.8%	36.4%	35.2%	33.2%
TERMINAL (d)	8/15 (53%)	8/25 (32%)	7/26 (27%)	8/22 (36%)
FIRST INCIDENCE	519	524	541	385
STATISTICAL TESTS				
LIFE TABLE	P=0.172N	P=0.138N	P=0.122N	P=0.124N
POLY 3	P=0.224N	P=0.304N	P=0.265N	P=0.211N
POLY 1.5	P=0.260N	P=0.397N	P=0.377N	P=0.273N
POLY 6	P=0.222N	P=0.196N	P=0.160N	P=0.168N
LOGISTIC REGRESSION	P=0.257N	P=0.307N	P=0.295N	P=0.240N
COCH-ARM / FISHERS	P=0.414N	P=0.513N	P=0.586N	P=0.436N
ORDER RESTRICTED	P=0.249N	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Thyroid Gland: C-Cell Carcinoma				
TUMOR RATES				
OVERALL (a)	0/52 (0%)	1/55 (2%)	2/52 (4%)	0/51 (0%)
POLY-3 RATE (b)	0/31.37	1/38.53	2/39.64	0/36.51
POLY-3 PERCENT (g)	0.0%	2.6%	5.1%	0.0%
TERMINAL (d)	0/15 (0%)	1/25 (4%)	1/26 (4%)	0/22 (0%)
FIRST INCIDENCE	---	727 (T)	709	---
STATISTICAL TESTS				
LIFE TABLE	P=0.583N	P=0.602	P=0.368	(e)
POLY 3	P=0.586N	P=0.541	P=0.292	(e)
POLY 1.5	P=0.602N	P=0.527	P=0.272	(e)
POLY 6	P=0.576N	P=0.561	P=0.318	(e)
LOGISTIC REGRESSION	P=0.599N	P=0.602	P=0.341	(e)
COCH-ARM / FISHERS	P=0.612	P=0.514	P=0.248	(e)
ORDER RESTRICTED	P=0.356N	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Thyroid Gland: C-Cell Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	15/52 (29%)	16/55 (29%)	17/52 (33%)	13/51 (25%)
POLY-3 RATE (b)	15/33.48	16/41.22	17/42.73	13/39.21
POLY-3 PERCENT (g)	44.8%	38.8%	39.8%	33.2%
TERMINAL (d)	8/15 (53%)	9/25 (36%)	8/26 (31%)	8/22 (36%)
FIRST INCIDENCE	519	524	541	385
STATISTICAL TESTS				
LIFE TABLE	P=0.168N	P=0.176N	P=0.200N	P=0.124N
POLY 3	P=0.214N	P=0.385N	P=0.417N	P=0.211N
POLY 1.5	P=0.253N	P=0.482N	P=0.543N	P=0.273N
POLY 6	P=0.211N	P=0.261N	P=0.278N	P=0.168N
LOGISTIC REGRESSION	P=0.250N	P=0.378N	P=0.436N	P=0.240N
COCH-ARM / FISHERS	P=0.419N	P=0.574	P=0.416	P=0.436N
ORDER RESTRICTED	P=0.252N	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Uterus Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/53 (0%)	3/55 (5%)	1/53 (2%)	1/53 (2%)
POLY-3 RATE (b)	0/31.38	3/38.64	1/39.86	1/37.32
POLY-3 PERCENT (g)	0.0%	7.8%	2.5%	2.7%
TERMINAL (d)	0/15 (0%)	2/25 (8%)	0/26 (0%)	1/22 (5%)
FIRST INCIDENCE	---	700	659	727 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.497N	P=0.228	P=0.568	P=0.576
POLY 3	P=0.475N	P=0.159	P=0.547	P=0.534
POLY 1.5	P=0.502N	P=0.144	P=0.531	P=0.525
POLY 6	P=0.451N	P=0.183	P=0.567	P=0.543
LOGISTIC REGRESSION	P=0.512N	P=0.206	P=0.535	P=0.576
COCH-ARM / FISHERS	P=0.562N	P=0.129	P=0.500	P=0.500
ORDER RESTRICTED	P=0.274	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Uterus Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/53 (8%)	5/55 (9%)	7/53 (13%)	3/53 (6%)
POLY-3 RATE (b)	4/31.79	5/39.02	7/40.14	3/37.58
POLY-3 PERCENT (g)	12.6%	12.8%	17.4%	8.0%
TERMINAL (d)	2/15 (13%)	2/25 (8%)	4/26 (15%)	2/22 (9%)
FIRST INCIDENCE	660	630	652	658
STATISTICAL TESTS				
LIFE TABLE	P=0.326N	P=0.479N	P=0.591	P=0.328N
POLY 3	P=0.363N	P=0.628	P=0.407	P=0.408N
POLY 1.5	P=0.379N	P=0.584	P=0.353	P=0.432N
POLY 6	P=0.369N	P=0.591N	P=0.474	P=0.387N
LOGISTIC REGRESSION	P=0.355N	P=0.585N	P=0.497	P=0.369N
COCH-ARM / FISHERS	P=0.460N	P=0.524	P=0.263	P=0.500N
ORDER RESTRICTED	P=0.350N	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
Uterus Sarcoma Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/53 (0%)	0/55 (0%)	0/53 (0%)	2/53 (4%)
POLY-3 RATE (b)	0/31.38	0/38.53	0/39.60	2/37.58
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	5.3%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	1/22 (5%)
FIRST INCIDENCE	---	---	---	658
STATISTICAL TESTS				
LIFE TABLE	P=0.055	(e)	(e)	P=0.322
POLY 3	P=0.049 *	(e)	(e)	P=0.279
POLY 1.5	P=0.048 *	(e)	(e)	P=0.267
POLY 6	P=0.049 *	(e)	(e)	P=0.291
LOGISTIC REGRESSION	P=0.049 *	(e)	(e)	P=0.285
COCH-ARM / FISHERS	P=0.045 *	(e)	(e)	P=0.248
ORDER RESTRICTED	P=0.047 *	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
		Females		
Uterus Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/53 (8%)	5/55 (9%)	7/53 (13%)	5/53 (9%)
POLY-3 RATE (b)	4/31.79	5/39.02	7/40.14	5/37.84
POLY-3 PERCENT (g)	12.6%	12.8%	17.4%	13.2%
TERMINAL (d)	2/15 (13%)	2/25 (8%)	4/26 (15%)	3/22 (14%)
FIRST INCIDENCE	660	630	652	658
STATISTICAL TESTS				
LIFE TABLE	P=0.518	P=0.479N	P=0.591	P=0.571N
POLY 3	P=0.476	P=0.628	P=0.407	P=0.610
POLY 1.5	P=0.458	P=0.584	P=0.353	P=0.580
POLY 6	P=0.476	P=0.591N	P=0.474	P=0.638
LOGISTIC REGRESSION	P=0.476	P=0.585N	P=0.497	P=0.636N
COCH-ARM / FISHERS	P=0.373	P=0.524	P=0.263	P=0.500
ORDER RESTRICTED	P=0.584	(e)	(e)	(e)

Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
		Females		
All Organs Hemangiosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/53 (4%)	0/55 (0%)	0/53 (0%)	1/53 (2%)
POLY-3 RATE (b)	2/31.60	0/38.53	0/39.60	1/37.32
POLY-3 PERCENT (g)	6.3%	0.0%	0.0%	2.7%
TERMINAL (d)	1/15 (7%)	0/25 (0%)	0/26 (0%)	1/22 (5%)
FIRST INCIDENCE	671	---	---	727 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.399N	P=0.139N	P=0.138N	P=0.390N
POLY 3	P=0.465N	P=0.195N	P=0.190N	P=0.442N
POLY 1.5	P=0.455N	P=0.208N	P=0.206N	P=0.457N
POLY 6	P=0.486N	P=0.177N	P=0.174N	P=0.429N
LOGISTIC REGRESSION	P=0.407N	P=0.168N	P=0.164N	P=0.409N
COCH-ARM / FISHERS	P=0.449N	P=0.238N	P=0.248N	P=0.500N
ORDER RESTRICTED	P=0.093N	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
All Organs Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/53 (0%)	2/55 (4%)	0/53 (0%)	2/53 (4%)
POLY-3 RATE (b)	0/31.38	2/40.04	0/39.60	2/37.84
POLY-3 PERCENT (g)	0.0%	5.0%	0.0%	5.3%
TERMINAL (d)	0/15 (0%)	0/25 (0%)	0/26 (0%)	0/22 (0%)
FIRST INCIDENCE	---	82	---	658
STATISTICAL TESTS				
LIFE TABLE	P=0.347	P=0.265	(e)	P=0.316
POLY 3	P=0.368	P=0.294	(e)	P=0.280
POLY 1.5	P=0.348	P=0.275	(e)	P=0.268
POLY 6	P=0.392	P=0.324	(e)	P=0.295
LOGISTIC REGRESSION	P=0.219	P=0.195	(e)	P=0.269
COCH-ARM / FISHERS	P=0.302	P=0.257	(e)	P=0.248
ORDER RESTRICTED	P=0.150	(e)	(e)	(e)

Dose	Females 0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
All Organs Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	45/53 (85%)	45/55 (82%)	48/53 (91%)	45/53 (85%)
POLY-3 RATE (b)	45/45.97	45/47.51	48/51.17	45/48.55
POLY-3 PERCENT (g)	97.9%	94.7%	93.8%	92.7%
TERMINAL (d)	15/15 (100%)	24/25 (96%)	23/26 (89%)	21/22 (96%)
FIRST INCIDENCE	309	356	188	385
STATISTICAL TESTS				
LIFE TABLE	P=0.156N	P=0.016N*	P=0.032N*	P=0.068N
POLY 3	P=0.162N	P=0.377N	P=0.296N	P=0.180N
POLY 1.5	P=0.220N	P=0.381N	P=0.480N	P=0.234N
POLY 6	P=0.239N	P=0.336N	P=0.201N	P=0.260N
LOGISTIC REGRESSION	P=0.211N	P=0.158N	P=0.613N	P=0.117N
COCH-ARM / FISHERS	P=0.373	P=0.432N	P=0.278	P=0.607N
ORDER RESTRICTED	P=0.156N	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

	Females			
Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
All Organs				
Malignant Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	13/53 (25%)	19/55 (35%)	18/53 (34%)	15/53 (28%)
POLY-3 RATE (b)	13/35.14	19/45.38	18/44.03	15/40.97
POLY-3 PERCENT (g)	37.0%	41.9%	40.9%	36.6%
TERMINAL (d)	5/15 (33%)	6/25 (24%)	8/26 (31%)	8/22 (36%)
FIRST INCIDENCE	176	82	236	448
STATISTICAL TESTS				
LIFE TABLE	P=0.352N	P=0.555	P=0.483N	P=0.425N
POLY 3	P=0.442N	P=0.414	P=0.451	P=0.583N
POLY 1.5	P=0.481N	P=0.312	P=0.343	P=0.543
POLY 6	P=0.429N	P=0.561	P=0.592	P=0.520N
LOGISTIC REGRESSION	P=0.478	P=0.162	P=0.244	P=0.500
COCH-ARM / FISHERS	P=0.474	P=0.177	P=0.197	P=0.413
ORDER RESTRICTED	P=0.592N	(e)	(e)	(e)

	Females			
Dose	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG
All Organs				
Malignant and Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	49/53 (92%)	51/55 (93%)	51/53 (96%)	47/53 (89%)
POLY-3 RATE (b)	49/49.21	51/52.35	51/52.14	47/49.77
POLY-3 PERCENT (g)	99.6%	97.4%	97.8%	94.4%
TERMINAL (d)	15/15 (100%)	24/25 (96%)	25/26 (96%)	21/22 (96%)
FIRST INCIDENCE	176	82	188	385
STATISTICAL TESTS				
LIFE TABLE	P=0.073N	P=0.036N*	P=0.021N*	P=0.043N*
POLY 3	P=0.081N	P=0.466N	P=0.543N	P=0.125N
POLY 1.5	P=0.092N	P=0.452N	P=0.654N	P=0.134N
POLY 6	P=0.160N	P=0.507N	P=0.515N	P=0.229N
LOGISTIC REGRESSION	P=0.089N	P=0.547N	P=0.661	P=0.066N
COCH-ARM / FISHERS	P=0.323N	P=0.621	P=0.339	P=0.371N
ORDER RESTRICTED	P=0.047N*	(e)	(e)	(e)

(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).

FINAL #2 RATS CTRL VS GRPS 6, 7, & 8

REASONS FOR REMOVAL:
25022 Accidently Killed
25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:

INCLUDE 001	0 NG/KG	
INCLUDE 006	300	NG/KG
INCLUDE 007	550	NG/KG
INCLUDE 008	1000	NG/KG

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 01
TEST TYPE: CHRONIC
CONT: N01-ES-75411
PATHOLOGIST: MISSING
Rats(SPRAGUE-DAWLEY)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 11:33:39

NTP C#: 96007D
CAS: 57465-28-8

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
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Ovary
Pancreas
Parathyroid Gland
Pituitary Gland
Salivary Glands
Thyroid Gland

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 01
TEST TYPE: CHRONIC
CONT: N01-ES-75411
PATHOLOGIST: MISSING

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 11:33:39

NTP C#: 96007D
CAS: 57465-28-8

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TOXIC EQUIVALENCY FACTOR EVALUATION (

Female Rats

Organ	Morphology
Adrenal Cortex	Adenoma
Adrenal Medulla	Pheochromocytoma Benign
	Pheochromocytoma: Benign, Complex, Malignant, NOS
Brain	Oligodendroglioma, Glioma, or Astrocytoma
Liver	Cholangiocarcinoma
	Cholangioma
	Hepatocholangioma
Lung	Cystic Keratinizing Epithelioma
	Squamous Cell Carcinoma
Mammary Gland	Carcinoma
	Carcinoma or Adenoma
	Fibroadenoma
	Fibroma, Fibroadenoma or Adenoma
	Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)	Squamous Cell Carcinoma
	Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma
Oral Mucosa	Squamous Cell Carcinoma
Pituitary Gland: Pars Distalis or Unspecified Site	Adenoma
	Carcinoma or Adenoma
Thyroid Gland: C-Cell	Adenoma
All Organs	Hemangiosarcoma
	Benign Tumors
	Malignant Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Adrenal Cortex Adenoma				
TUMOR RATES				
OVERALL (a)	0/52 (0%)	0/53 (0%)	1/52 (2%)	2/53 (4%)
POLY-3 RATE (b)	0/31.36	0/36.61	1/41.55	2/32.75
POLY-3 PERCENT (g)	0.0%	0.0%	2.4%	6.1%
TERMINAL (d)	0/15 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	722	603
STATISTICAL TESTS				
LIFE TABLE	P=0.046 *	(e)	P=0.602	P=0.276
POLY 3	P=0.067	(e)	P=0.555	P=0.245
POLY 1.5	P=0.069	(e)	P=0.536	P=0.247
POLY 6	P=0.061	(e)	P=0.576	P=0.233
LOGISTIC REGRESSION	P=0.066	(e)	P=0.609	P=0.243
COCH-ARM / FISHERS	P=0.070	(e)	P=0.500	P=0.252
ORDER RESTRICTED	P=0.079	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Adrenal Cortex Carcinoma				
TUMOR RATES				
OVERALL (a)	0/52 (0%)	1/53 (2%)	0/52 (0%)	2/53 (4%)
POLY-3 RATE (b)	0/31.36	1/37.02	0/41.53	2/32.51
POLY-3 PERCENT (g)	0.0%	2.7%	0.0%	6.2%
TERMINAL (d)	0/15 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	607	---	588
STATISTICAL TESTS				
LIFE TABLE	P=0.124	P=0.561	(e)	P=0.229
POLY 3	P=0.149	P=0.533	(e)	P=0.243
POLY 1.5	P=0.147	P=0.522	(e)	P=0.246
POLY 6	P=0.150	P=0.545	(e)	P=0.229
LOGISTIC REGRESSION	P=0.137	P=0.508	(e)	P=0.241
COCH-ARM / FISHERS	P=0.140	P=0.505	(e)	P=0.252
ORDER RESTRICTED	P=0.078	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Adrenal Medulla Pheochromocytoma Benign				
TUMOR RATES				
OVERALL (a)	8/52 (15%)	2/53 (4%)	4/52 (8%)	0/53 (0%)
POLY-3 RATE (b)	8/33.26	2/36.68	4/42.10	0/31.91
POLY-3 PERCENT (g)	24.1%	5.5%	9.5%	0.0%
TERMINAL (d)	3/15 (20%)	1/16 (6%)	2/23 (9%)	0/7 (0%)
FIRST INCIDENCE	531	709	618	---
STATISTICAL TESTS				
LIFE TABLE	P=0.005N**	P=0.031N*	P=0.047N*	P=0.018N*
POLY 3	P=0.004N**	P=0.027N*	P=0.081N	P=0.003N**
POLY 1.5	P=0.004N**	P=0.032N*	P=0.107N	P=0.003N**
POLY 6	P=0.004N**	P=0.024N*	P=0.059N	P=0.005N**
LOGISTIC REGRESSION	P=0.003N**	P=0.026N*	P=0.087N	P=0.004N**
COCH-ARM / FISHERS	P=0.004N**	P=0.043N*	P=0.179N	P=0.003N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Adrenal Medulla Pheochromocytoma: Benign, Complex, Malignant, NOS				
TUMOR RATES				
OVERALL (a)	8/52 (15%)	3/53 (6%)	5/52 (10%)	0/53 (0%)
POLY-3 RATE (b)	8/33.26	3/36.68	5/42.10	0/31.91
POLY-3 PERCENT (g)	24.1%	8.2%	11.9%	0.0%
TERMINAL (d)	3/15 (20%)	2/16 (13%)	3/23 (13%)	0/7 (0%)
FIRST INCIDENCE	531	709	618	---
STATISTICAL TESTS				
LIFE TABLE	P=0.008N**	P=0.067N	P=0.081N	P=0.018N*
POLY 3	P=0.005N**	P=0.064N	P=0.140N	P=0.003N**
POLY 1.5	P=0.005N**	P=0.073N	P=0.179N	P=0.003N**
POLY 6	P=0.007N**	P=0.060N	P=0.107N	P=0.005N**
LOGISTIC REGRESSION	P=0.004N**	P=0.056N	P=0.140N	P=0.004N**
COCH-ARM / FISHERS	P=0.006N**	P=0.095N	P=0.277N	P=0.003N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Brain				
Astrocytoma Malignant				
TUMOR RATES				
OVERALL (a)	2/53 (4%)	1/53 (2%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	2/31.82	1/37.19	0/42.13	0/31.91
POLY-3 PERCENT (g)	6.3%	2.7%	0.0%	0.0%
TERMINAL (d)	1/15 (7%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	600	541	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.077N	P=0.448N	P=0.158N	P=0.301N
POLY 3	P=0.077N	P=0.445N	P=0.181N	P=0.235N
POLY 1.5	P=0.080N	P=0.464N	P=0.198N	P=0.231N
POLY 6	P=0.069N	P=0.429N	P=0.165N	P=0.254N
LOGISTIC REGRESSION	P=0.082N	P=0.480N	P=0.185N	P=0.240N
COCH-ARM / FISHERS	P=0.086N	P=0.500N	P=0.248N	P=0.248N
ORDER RESTRICTED	P=0.073N	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Brain				
Oligodendroglioma, Glioma, or Astrocytoma				
TUMOR RATES				
OVERALL (a)	3/53 (6%)	1/53 (2%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	3/32.80	1/37.19	0/42.13	0/31.91
POLY-3 PERCENT (g)	9.2%	2.7%	0.0%	0.0%
TERMINAL (d)	1/15 (7%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	201	541	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.030N*	P=0.270N	P=0.080N	P=0.156N
POLY 3	P=0.029N*	P=0.260N	P=0.080N	P=0.121N
POLY 1.5	P=0.031N*	P=0.276N	P=0.092N	P=0.117N
POLY 6	P=0.025N*	P=0.245N	P=0.069N	P=0.138N
LOGISTIC REGRESSION	P=0.043N*	P=0.338N	P=0.177N	P=0.128N
COCH-ARM / FISHERS	P=0.034N*	P=0.309N	P=0.121N	P=0.121N
ORDER RESTRICTED	P=0.021N*	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Heart				
Schwannoma Malignant				
TUMOR RATES				
OVERALL (a)	0/52 (0%)	2/53 (4%)	0/51 (0%)	0/51 (0%)
POLY-3 RATE (b)	0/31.37	2/36.86	0/41.13	0/30.95
POLY-3 PERCENT (g)	0.0%	5.4%	0.0%	0.0%
TERMINAL (d)	0/15 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	680	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.471N	P=0.303	(e)	(e)
POLY 3	P=0.376N	P=0.274	(e)	(e)
POLY 1.5	P=0.395N	P=0.261	(e)	(e)
POLY 6	P=0.352N	P=0.287	(e)	(e)
LOGISTIC REGRESSION	P=0.432N	P=0.282	(e)	(e)
COCH-ARM / FISHERS	P=0.429N	P=0.252	(e)	(e)
ORDER RESTRICTED	P=0.281N	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Kidney: Renal Tubule				
Nephroblastoma				
TUMOR RATES				
OVERALL (a)	1/53 (2%)	0/53 (0%)	0/52 (0%)	2/53 (4%)
POLY-3 RATE (b)	1/32.37	0/36.61	0/41.53	2/33.85
POLY-3 PERCENT (g)	3.1%	0.0%	0.0%	5.9%
TERMINAL (d)	0/15 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	176	---	---	188
STATISTICAL TESTS				
LIFE TABLE	P=0.276	P=0.504N	P=0.496N	P=0.509
POLY 3	P=0.271	P=0.475N	P=0.451N	P=0.516
POLY 1.5	P=0.272	P=0.485N	P=0.469N	P=0.517
POLY 6	P=0.270	P=0.467N	P=0.431N	P=0.493
LOGISTIC REGRESSION	P=0.214	P=0.494N	P=0.849N	P=0.435
COCH-ARM / FISHERS	P=0.269	P=0.500N	P=0.505N	P=0.500
ORDER RESTRICTED	P=0.132	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Liver Cholangiocarcinoma				
TUMOR RATES				
OVERALL (a)	0/53 (0%)	5/53 (9%)	6/51 (12%)	22/53 (42%)
POLY-3 RATE (b)	0/31.38	5/36.89	6/42.75	22/36.46
POLY-3 PERCENT (g)	0.0%	13.6%	14.0%	60.3%
TERMINAL (d)	0/15 (0%)	3/16 (19%)	1/23 (4%)	6/7 (86%)
FIRST INCIDENCE	---	659	618	562
STATISTICAL TESTS				
LIFE TABLE	P<0.001 **	P=0.047 *	P=0.068	P<0.001 **
POLY 3	P<0.001 **	P=0.045 *	P=0.040 *	P<0.001 **
POLY 1.5	P<0.001 **	P=0.039 *	P=0.028 *	P<0.001 **
POLY 6	P<0.001 **	P=0.050	P=0.060	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	P=0.052	P=0.026 *	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	P=0.028 *	P=0.012 *	P<0.001 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Liver Cholangioma				
TUMOR RATES				
OVERALL (a)	0/53 (0%)	0/53 (0%)	1/51 (2%)	2/53 (4%)
POLY-3 RATE (b)	0/31.38	0/36.61	1/41.43	2/31.91
POLY-3 PERCENT (g)	0.0%	0.0%	2.4%	6.3%
TERMINAL (d)	0/15 (0%)	0/16 (0%)	1/23 (4%)	2/7 (29%)
FIRST INCIDENCE	---	---	727 (T)	727 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.015 *	(e)	P=0.585	P=0.090
POLY 3	P=0.064	(e)	P=0.554	P=0.239
POLY 1.5	P=0.068	(e)	P=0.534	P=0.243
POLY 6	P=0.057	(e)	P=0.576	P=0.220
LOGISTIC REGRESSION	(e)	(e)	P=0.585	P=0.090
COCH-ARM / FISHERS	P=0.069	(e)	P=0.490	P=0.248
ORDER RESTRICTED	P=0.075	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Liver				
Hepatocellular Adenoma				
TUMOR RATES				
OVERALL (a)	1/53 (2%)	0/53 (0%)	1/51 (2%)	2/53 (4%)
POLY-3 RATE (b)	1/31.38	0/36.61	1/41.43	2/32.41
POLY-3 PERCENT (g)	3.2%	0.0%	2.4%	6.2%
TERMINAL (d)	1/15 (7%)	0/16 (0%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	727 (T)	---	727 (T)	621
STATISTICAL TESTS				
LIFE TABLE	P=0.162	P=0.487N	P=0.664N	P=0.384
POLY 3	P=0.249	P=0.469N	P=0.695N	P=0.511
POLY 1.5	P=0.255	P=0.480N	P=0.721N	P=0.513
POLY 6	P=0.237	P=0.460N	P=0.665N	P=0.491
LOGISTIC REGRESSION	P=0.224	(e)	P=0.664N	P=0.471
COCH-ARM / FISHERS	P=0.256	P=0.500N	P=0.743	P=0.500
ORDER RESTRICTED	P=0.223	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Liver				
Hepatocholangioma				
TUMOR RATES				
OVERALL (a)	0/53 (0%)	0/53 (0%)	0/51 (0%)	2/53 (4%)
POLY-3 RATE (b)	0/31.38	0/36.61	0/41.43	2/32.40
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	6.2%
TERMINAL (d)	0/15 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	660
STATISTICAL TESTS				
LIFE TABLE	P=0.028 *	(e)	(e)	P=0.206
POLY 3	P=0.050	(e)	(e)	P=0.243
POLY 1.5	P=0.050	(e)	(e)	P=0.245
POLY 6	P=0.049 *	(e)	(e)	P=0.228
LOGISTIC REGRESSION	P=0.044 *	(e)	(e)	P=0.233
COCH-ARM / FISHERS	P=0.050	(e)	(e)	P=0.248
ORDER RESTRICTED	P=0.031 *	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Lung Cystic Keratinizing Epithelioma				
TUMOR RATES				
OVERALL (a)	0/53 (0%)	1/53 (2%)	11/51 (22%)	35/51 (69%)
POLY-3 RATE (b)	0/31.38	1/36.61	11/42.26	35/41.94
POLY-3 PERCENT (g)	0.0%	2.7%	26.0%	83.5%
TERMINAL (d)	0/15 (0%)	1/16 (6%)	5/23 (22%)	6/7 (86%)
FIRST INCIDENCE	---	727 (T)	588	484
STATISTICAL TESTS				
LIFE TABLE	P<0.001 **	P=0.513	P=0.009 **	P<0.001 **
POLY 3	P<0.001 **	P=0.531	P=0.002 **	P<0.001 **
POLY 1.5	P<0.001 **	P=0.520	P<0.001 **	P<0.001 **
POLY 6	P<0.001 **	P=0.540	P=0.005 **	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	P=0.513	P=0.004 **	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	P=0.500	P<0.001 **	P<0.001 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Lung Squamous Cell Carcinoma				
TUMOR RATES				
OVERALL (a)	0/53 (0%)	0/53 (0%)	1/51 (2%)	2/51 (4%)
POLY-3 RATE (b)	0/31.38	0/36.61	1/41.13	2/31.91
POLY-3 PERCENT (g)	0.0%	0.0%	2.4%	6.3%
TERMINAL (d)	0/15 (0%)	0/16 (0%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	---	---	727 (T)	555
STATISTICAL TESTS				
LIFE TABLE	P=0.046 *	(e)	P=0.585	P=0.265
POLY 3	P=0.064	(e)	P=0.553	P=0.239
POLY 1.5	P=0.065	(e)	P=0.532	P=0.238
POLY 6	P=0.059	(e)	P=0.575	P=0.229
LOGISTIC REGRESSION	P=0.063	(e)	P=0.585	P=0.230
COCH-ARM / FISHERS	P=0.064	(e)	P=0.490	P=0.238
ORDER RESTRICTED	P=0.075	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Mammary Gland Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/53 (4%)	1/53 (2%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	2/31.38	1/36.61	0/42.13	0/31.91
POLY-3 PERCENT (g)	6.4%	2.7%	0.0%	0.0%
TERMINAL (d)	2/15 (13%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.095N	P=0.477N	P=0.149N	P=0.416N
POLY 3	P=0.076N	P=0.446N	P=0.178N	P=0.232N
POLY 1.5	P=0.080N	P=0.465N	P=0.197N	P=0.229N
POLY 6	P=0.069N	P=0.429N	P=0.160N	P=0.248N
LOGISTIC REGRESSION	P=0.095N	P=0.477N	(e)	(e)
COCH-ARM / FISHERS	P=0.086N	P=0.500N	P=0.248N	P=0.248N
ORDER RESTRICTED	P=0.071N	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Mammary Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	6/53 (11%)	0/53 (0%)	1/53 (2%)	1/53 (2%)
POLY-3 RATE (b)	6/32.44	0/36.61	1/42.13	1/32.91
POLY-3 PERCENT (g)	18.5%	0.0%	2.4%	3.0%
TERMINAL (d)	3/15 (20%)	0/16 (0%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	400	---	727 (T)	72
STATISTICAL TESTS				
LIFE TABLE	P=0.035N*	P=0.012N*	P=0.015N*	P=0.160N
POLY 3	P=0.025N*	P=0.009N**	P=0.024N*	P=0.049N*
POLY 1.5	P=0.026N*	P=0.011N*	P=0.032N*	P=0.048N*
POLY 6	P=0.023N*	P=0.007N**	P=0.017N*	P=0.059N
LOGISTIC REGRESSION	P=0.030N*	P=0.011N*	P=0.024N*	P=0.058N
COCH-ARM / FISHERS	P=0.029N*	P=0.013N*	P=0.056N	P=0.056N
ORDER RESTRICTED	P=0.002N**	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Mammary Gland Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	7/53 (13%)	1/53 (2%)	1/53 (2%)	1/53 (2%)
POLY-3 RATE (b)	7/32.44	1/36.61	1/42.13	1/32.91
POLY-3 PERCENT (g)	21.6%	2.7%	2.4%	3.0%
TERMINAL (d)	4/15 (27%)	1/16 (6%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	400	727 (T)	727 (T)	72
STATISTICAL TESTS				
LIFE TABLE	P=0.015N*	P=0.022N*	P=0.006N**	P=0.117N
POLY 3	P=0.009N**	P=0.017N*	P=0.010N*	P=0.024N*
POLY 1.5	P=0.010N*	P=0.021N*	P=0.015N*	P=0.024N*
POLY 6	P=0.008N**	P=0.014N*	P=0.007N**	P=0.030N*
LOGISTIC REGRESSION	P=0.011N*	P=0.016N*	P=0.009N**	P=0.032N*
COCH-ARM / FISHERS	P=0.012N*	P=0.030N*	P=0.030N*	P=0.030N*
ORDER RESTRICTED	P=0.002N**	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Mammary Gland Fibroadenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	39/53 (74%)	39/53 (74%)	29/53 (55%)	11/53 (21%)
POLY-3 RATE (b)	39/45.19	39/48.22	29/46.84	11/35.90
POLY-3 PERCENT (g)	86.3%	80.9%	61.9%	30.6%
TERMINAL (d)	11/15 (73%)	10/16 (63%)	14/23 (61%)	3/7 (43%)
FIRST INCIDENCE	309	247	440	258
STATISTICAL TESTS				
LIFE TABLE	P<0.001N**	P=0.250N	P<0.001N**	P<0.001N**
POLY 3	P<0.001N**	P=0.327N	P=0.004N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.387N	P=0.005N**	P<0.001N**
POLY 6	P<0.001N**	P=0.304N	P=0.006N**	P<0.001N**
LOGISTIC REGRESSION	P<0.001N**	P=0.445N	P=0.004N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.587N	P=0.034N*	P<0.001N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Mammary Gland Fibroma, Fibroadenoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	40/53 (75%)	39/53 (74%)	29/53 (55%)	11/53 (21%)
POLY-3 RATE (b)	40/45.19	39/48.22	29/46.84	11/35.90
POLY-3 PERCENT (g)	88.5%	80.9%	61.9%	30.6%
TERMINAL (d)	12/15 (80%)	10/16 (63%)	14/23 (61%)	3/7 (43%)
FIRST INCIDENCE	309	247	440	258
STATISTICAL TESTS				
LIFE TABLE	P<0.001N**	P=0.210N	P<0.001N**	P<0.001N**
POLY 3	P<0.001N**	P=0.219N	P=0.002N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.279N	P=0.002N**	P<0.001N**
POLY 6	P<0.001N**	P=0.195N	P=0.002N**	P<0.001N**
LOGISTIC REGRESSION	P<0.001N**	P=0.344N	P=0.002N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500N	P=0.020N*	P<0.001N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	42/53 (79%)	39/53 (74%)	29/53 (55%)	12/53 (23%)
POLY-3 RATE (b)	42/46.17	39/48.22	29/46.84	12/36.90
POLY-3 PERCENT (g)	91.0%	80.9%	61.9%	32.5%
TERMINAL (d)	12/15 (80%)	10/16 (63%)	14/23 (61%)	3/7 (43%)
FIRST INCIDENCE	309	247	440	72
STATISTICAL TESTS				
LIFE TABLE	P<0.001N**	P=0.143N	P<0.001N**	P<0.001N**
POLY 3	P<0.001N**	P=0.121N	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.149N	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.118N	P<0.001N**	P<0.001N**
LOGISTIC REGRESSION	P<0.001N**	P=0.191N	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.324N	P=0.006N**	P<0.001N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/53 (0%)	2/53 (4%)	2/53 (4%)	7/53 (13%)
POLY-3 RATE (b)	0/31.38	2/36.99	2/42.83	7/34.71
POLY-3 PERCENT (g)	0.0%	5.4%	4.7%	20.2%
TERMINAL (d)	0/15 (0%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	618	498	523
STATISTICAL TESTS				
LIFE TABLE	P<0.001 **	P=0.280	P=0.328	P=0.011 *
POLY 3	P=0.002 **	P=0.275	P=0.312	P=0.010 *
POLY 1.5	P=0.002 **	P=0.261	P=0.285	P=0.009 **
POLY 6	P=0.002 **	P=0.289	P=0.342	P=0.009 **
LOGISTIC REGRESSION	P=0.002 **	P=0.271	P=0.225	P=0.010 *
COCH-ARM / FISHERS	P=0.002 **	P=0.248	P=0.248	P=0.006 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/53 (0%)	2/53 (4%)	2/53 (4%)	7/53 (13%)
POLY-3 RATE (b)	0/31.38	2/36.99	2/42.83	7/34.71
POLY-3 PERCENT (g)	0.0%	5.4%	4.7%	20.2%
TERMINAL (d)	0/15 (0%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	618	498	523
STATISTICAL TESTS				
LIFE TABLE	P<0.001 **	P=0.280	P=0.328	P=0.011 *
POLY 3	P=0.002 **	P=0.275	P=0.312	P=0.010 *
POLY 1.5	P=0.002 **	P=0.261	P=0.285	P=0.009 **
POLY 6	P=0.002 **	P=0.289	P=0.342	P=0.009 **
LOGISTIC REGRESSION	P=0.002 **	P=0.271	P=0.225	P=0.010 *
COCH-ARM / FISHERS	P=0.002 **	P=0.248	P=0.248	P=0.006 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Oral Mucosa Squamous Cell Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/53 (0%)	2/53 (4%)	2/53 (4%)	7/53 (13%)
POLY-3 RATE (b)	0/31.38	2/36.99	2/42.83	7/34.71
POLY-3 PERCENT (g)	0.0%	5.4%	4.7%	20.2%
TERMINAL (d)	0/15 (0%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	618	498	523
STATISTICAL TESTS				
LIFE TABLE	P<0.001 **	P=0.280	P=0.328	P=0.011 *
POLY 3	P=0.002 **	P=0.275	P=0.312	P=0.010 *
POLY 1.5	P=0.002 **	P=0.261	P=0.285	P=0.009 **
POLY 6	P=0.002 **	P=0.289	P=0.342	P=0.009 **
LOGISTIC REGRESSION	P=0.002 **	P=0.271	P=0.225	P=0.010 *
COCH-ARM / FISHERS	P=0.002 **	P=0.248	P=0.248	P=0.006 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Pancreas Adenoma				
TUMOR RATES				
OVERALL (a)	1/51 (2%)	2/53 (4%)	0/52 (0%)	0/51 (0%)
POLY-3 RATE (b)	1/31.35	2/36.63	0/41.53	0/30.95
POLY-3 PERCENT (g)	3.2%	5.5%	0.0%	0.0%
TERMINAL (d)	1/15 (7%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	727 (T)	722	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.232N	P=0.536	P=0.415N	P=0.652N
POLY 3	P=0.162N	P=0.554	P=0.445N	P=0.503N
POLY 1.5	P=0.171N	P=0.538	P=0.463N	P=0.500N
POLY 6	P=0.149N	P=0.572	P=0.424N	P=0.516N
LOGISTIC REGRESSION	P=0.208N	P=0.571	(e)	(e)
COCH-ARM / FISHERS	P=0.186N	P=0.515	P=0.495N	P=0.500N
ORDER RESTRICTED	P=0.200N	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Pancreas Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	1/51 (2%)	2/53 (4%)	0/52 (0%)	1/51 (2%)
POLY-3 RATE (b)	1/31.35	2/36.63	0/41.53	1/31.19
POLY-3 PERCENT (g)	3.2%	5.5%	0.0%	3.2%
TERMINAL (d)	1/15 (7%)	1/16 (6%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	727 (T)	722	---	663
STATISTICAL TESTS				
LIFE TABLE	P=0.607N	P=0.536	P=0.415N	P=0.665
POLY 3	P=0.452N	P=0.554	P=0.445N	P=0.761
POLY 1.5	P=0.466N	P=0.538	P=0.463N	P=0.760N
POLY 6	P=0.429N	P=0.572	P=0.424N	P=0.750
LOGISTIC REGRESSION	P=0.539N	P=0.571	(e)	P=0.727
COCH-ARM / FISHERS	P=0.489N	P=0.515	P=0.495N	P=0.752N
ORDER RESTRICTED	P=0.394N	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma				
TUMOR RATES				
OVERALL (a)	15/51 (29%)	22/53 (42%)	14/53 (26%)	6/53 (11%)
POLY-3 RATE (b)	15/32.57	22/39.95	14/43.88	6/32.96
POLY-3 PERCENT (g)	46.1%	55.1%	31.9%	18.2%
TERMINAL (d)	9/15 (60%)	10/16 (63%)	7/23 (30%)	1/7 (14%)
FIRST INCIDENCE	603	531	588	607
STATISTICAL TESTS				
LIFE TABLE	P=0.044N*	P=0.261	P=0.082N	P=0.214N
POLY 3	P=0.002N**	P=0.289	P=0.150N	P=0.011N*
POLY 1.5	P=0.002N**	P=0.221	P=0.234N	P=0.011N*
POLY 6	P=0.002N**	P=0.372	P=0.087N	P=0.015N*
LOGISTIC REGRESSION	P=0.003N**	P=0.298	P=0.100N	P=0.028N*
COCH-ARM / FISHERS	P=0.005N**	P=0.139	P=0.451N	P=0.019N*
ORDER RESTRICTED	P=0.004N**	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	15/51 (29%)	22/53 (42%)	15/53 (28%)	6/53 (11%)
POLY-3 RATE (b)	15/32.57	22/39.95	15/43.88	6/32.96
POLY-3 PERCENT (g)	46.1%	55.1%	34.2%	18.2%
TERMINAL (d)	9/15 (60%)	10/16 (63%)	8/23 (35%)	1/7 (14%)
FIRST INCIDENCE	603	531	588	607
STATISTICAL TESTS				
LIFE TABLE	P=0.051N	P=0.261	P=0.111N	P=0.214N
POLY 3	P=0.002N**	P=0.289	P=0.205N	P=0.011N*
POLY 1.5	P=0.002N**	P=0.221	P=0.304N	P=0.011N*
POLY 6	P=0.003N**	P=0.372	P=0.125N	P=0.015N*
LOGISTIC REGRESSION	P=0.003N**	P=0.298	P=0.135N	P=0.028N*
COCH-ARM / FISHERS	P=0.006N**	P=0.139	P=0.536N	P=0.019N*
ORDER RESTRICTED	P=0.004N**	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Thyroid Gland: C-Cell Adenoma				
TUMOR RATES				
OVERALL (a)	15/52 (29%)	12/52 (23%)	12/50 (24%)	9/48 (19%)
POLY-3 RATE (b)	15/33.48	12/38.97	12/42.47	9/33.10
POLY-3 PERCENT (g)	44.8%	30.8%	28.3%	27.2%
TERMINAL (d)	8/15 (53%)	3/16 (19%)	7/23 (30%)	1/7 (14%)
FIRST INCIDENCE	519	454	588	394
STATISTICAL TESTS				
LIFE TABLE	P=0.266N	P=0.194N	P=0.039N*	P=0.431N
POLY 3	P=0.096N	P=0.155N	P=0.101N	P=0.096N
POLY 1.5	P=0.109N	P=0.215N	P=0.173N	P=0.115N
POLY 6	P=0.098N	P=0.104N	P=0.053N	P=0.097N
LOGISTIC REGRESSION	P=0.115N	P=0.192N	P=0.067N	P=0.141N
COCH-ARM / FISHERS	P=0.156N	P=0.328N	P=0.371N	P=0.172N
ORDER RESTRICTED	P=0.101N	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Thyroid Gland: C-Cell Carcinoma				
TUMOR RATES				
OVERALL (a)	0/52 (0%)	0/52 (0%)	2/50 (4%)	0/48 (0%)
POLY-3 RATE (b)	0/31.37	0/35.79	2/41.02	0/29.95
POLY-3 PERCENT (g)	0.0%	0.0%	4.9%	0.0%
TERMINAL (d)	0/15 (0%)	0/16 (0%)	2/23 (9%)	0/7 (0%)
FIRST INCIDENCE	---	---	727 (T)	---
STATISTICAL TESTS				
LIFE TABLE	P=0.431	(e)	P=0.336	(e)
POLY 3	P=0.490	(e)	P=0.302	(e)
POLY 1.5	P=0.511	(e)	P=0.275	(e)
POLY 6	P=0.433	(e)	P=0.333	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.336	(e)
COCH-ARM / FISHERS	P=0.521	(e)	P=0.238	(e)
ORDER RESTRICTED	P=0.302	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Thyroid Gland: C-Cell Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	15/52 (29%)	12/52 (23%)	14/50 (28%)	9/48 (19%)
POLY-3 RATE (b)	15/33.48	12/38.97	14/42.47	9/33.10
POLY-3 PERCENT (g)	44.8%	30.8%	33.0%	27.2%
TERMINAL (d)	8/15 (53%)	3/16 (19%)	9/23 (39%)	1/7 (14%)
FIRST INCIDENCE	519	454	588	394
STATISTICAL TESTS				
LIFE TABLE	P=0.316N	P=0.194N	P=0.081N	P=0.431N
POLY 3	P=0.117N	P=0.155N	P=0.204N	P=0.096N
POLY 1.5	P=0.130N	P=0.215N	P=0.311N	P=0.115N
POLY 6	P=0.124N	P=0.104N	P=0.120N	P=0.097N
LOGISTIC REGRESSION	P=0.134N	P=0.192N	P=0.129N	P=0.141N
COCH-ARM / FISHERS	P=0.182N	P=0.328N	P=0.550N	P=0.172N
ORDER RESTRICTED	P=0.105N	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Uterus Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/53 (8%)	8/53 (15%)	5/53 (9%)	4/53 (8%)
POLY-3 RATE (b)	4/31.79	8/37.70	5/42.23	4/32.95
POLY-3 PERCENT (g)	12.6%	21.2%	11.8%	12.1%
TERMINAL (d)	2/15 (13%)	5/16 (31%)	4/23 (17%)	1/7 (14%)
FIRST INCIDENCE	660	541	700	621
STATISTICAL TESTS				
LIFE TABLE	P=0.483	P=0.250	P=0.491N	P=0.440
POLY 3	P=0.365N	P=0.263	P=0.601N	P=0.628N
POLY 1.5	P=0.372N	P=0.230	P=0.617	P=0.623N
POLY 6	P=0.379N	P=0.297	P=0.543N	P=0.641
LOGISTIC REGRESSION	P=0.439N	P=0.281	P=0.479N	P=0.613
COCH-ARM / FISHERS	P=0.416N	P=0.179	P=0.500	P=0.642N
ORDER RESTRICTED	P=0.445N	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Uterus Sarcoma Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/53 (0%)	2/53 (4%)	2/53 (4%)	0/53 (0%)
POLY-3 RATE (b)	0/31.38	2/36.68	2/42.18	0/31.91
POLY-3 PERCENT (g)	0.0%	5.5%	4.7%	0.0%
TERMINAL (d)	0/15 (0%)	1/16 (6%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	---	709	714	---
STATISTICAL TESTS				
LIFE TABLE	P=0.600	P=0.277	P=0.361	(e)
POLY 3	P=0.523N	P=0.273	P=0.308	(e)
POLY 1.5	P=0.521N	P=0.260	P=0.283	(e)
POLY 6	P=0.546N	P=0.285	P=0.337	(e)
LOGISTIC REGRESSION	P=0.636N	P=0.287	P=0.361	(e)
COCH-ARM / FISHERS	P=0.541N	P=0.248	P=0.248	(e)
ORDER RESTRICTED	P=0.325N	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Uterus				
Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/53 (8%)	10/53 (19%)	7/53 (13%)	4/53 (8%)
POLY-3 RATE (b)	4/31.79	10/37.77	7/42.29	4/32.95
POLY-3 PERCENT (g)	12.6%	26.5%	16.6%	12.1%
TERMINAL (d)	2/15 (13%)	6/16 (38%)	5/23 (22%)	1/7 (14%)
FIRST INCIDENCE	660	541	700	621
STATISTICAL TESTS				
LIFE TABLE	P=0.463	P=0.123	P=0.575	P=0.440
POLY 3	P=0.331N	P=0.124	P=0.443	P=0.628N
POLY 1.5	P=0.338N	P=0.103	P=0.379	P=0.623N
POLY 6	P=0.353N	P=0.146	P=0.511	P=0.641
LOGISTIC REGRESSION	P=0.426N	P=0.141	P=0.592	P=0.613
COCH-ARM / FISHERS	P=0.388N	P=0.075	P=0.263	P=0.642N
ORDER RESTRICTED	P=0.329N	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
Uterus				
Schwannoma Malignant				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/53 (0%)	1/53 (2%)	2/53 (4%)	0/53 (0%)
POLY-3 RATE (b)	0/31.38	1/36.86	2/42.23	0/31.91
POLY-3 PERCENT (g)	0.0%	2.7%	4.7%	0.0%
TERMINAL (d)	0/15 (0%)	0/16 (0%)	1/23 (4%)	0/7 (0%)
FIRST INCIDENCE	---	658	700	---
STATISTICAL TESTS				
LIFE TABLE	P=0.571	P=0.562	P=0.358	(e)
POLY 3	P=0.617	P=0.532	P=0.309	(e)
POLY 1.5	P=0.634	P=0.521	P=0.283	(e)
POLY 6	P=0.560	P=0.543	P=0.337	(e)
LOGISTIC REGRESSION	P=0.629	P=0.525	P=0.350	(e)
COCH-ARM / FISHERS	P=0.632	P=0.500	P=0.248	(e)
ORDER RESTRICTED	P=0.380N	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
All Organs Hemangiosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/53 (4%)	0/53 (0%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	2/31.60	0/36.61	0/42.13	0/31.91
POLY-3 PERCENT (g)	6.3%	0.0%	0.0%	0.0%
TERMINAL (d)	1/15 (7%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	671	---	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.079N	P=0.208N	P=0.138N	P=0.352N
POLY 3	P=0.083N	P=0.205N	P=0.179N	P=0.233N
POLY 1.5	P=0.086N	P=0.216N	P=0.197N	P=0.230N
POLY 6	P=0.073N	P=0.196N	P=0.163N	P=0.251N
LOGISTIC REGRESSION	P=0.072N	P=0.191N	P=0.151N	P=0.277N
COCH-ARM / FISHERS	P=0.087N	P=0.248N	P=0.248N	P=0.248N
ORDER RESTRICTED	P=0.028N*	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
All Organs Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/53 (0%)	1/53 (2%)	1/53 (2%)	2/53 (4%)
POLY-3 RATE (b)	0/31.38	1/37.22	1/42.64	2/32.66
POLY-3 PERCENT (g)	0.0%	2.7%	2.4%	6.1%
TERMINAL (d)	0/15 (0%)	0/16 (0%)	0/23 (0%)	0/7 (0%)
FIRST INCIDENCE	---	531	573	611
STATISTICAL TESTS				
LIFE TABLE	P=0.136	P=0.534	P=0.566	P=0.230
POLY 3	P=0.150	P=0.534	P=0.560	P=0.244
POLY 1.5	P=0.151	P=0.522	P=0.540	P=0.246
POLY 6	P=0.143	P=0.546	P=0.581	P=0.232
LOGISTIC REGRESSION	P=0.142	P=0.484	P=0.470	P=0.241
COCH-ARM / FISHERS	P=0.143	P=0.500	P=0.500	P=0.248
ORDER RESTRICTED	P=0.123	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
All Organs Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	45/53 (85%)	46/53 (87%)	45/53 (85%)	42/53 (79%)
POLY-3 RATE (b)	45/45.97	46/49.09	45/47.95	42/45.75
POLY-3 PERCENT (g)	97.9%	93.7%	93.8%	91.8%
TERMINAL (d)	15/15 (100%)	14/16 (88%)	23/23 (100%)	7/7 (100%)
FIRST INCIDENCE	309	247	440	258
STATISTICAL TESTS				
LIFE TABLE	P=0.253	P=0.258N	P=0.007N**	P=0.258
POLY 3	P=0.125N	P=0.285N	P=0.270N	P=0.135N
POLY 1.5	P=0.110N	P=0.424N	P=0.302N	P=0.152N
POLY 6	P=0.223N	P=0.218N	P=0.362N	P=0.188N
LOGISTIC REGRESSION	P=0.062N	P=0.454N	P=0.020N*	P=0.100N
COCH-ARM / FISHERS	P=0.214N	P=0.500	P=0.607N	P=0.307N
ORDER RESTRICTED	P=0.104N	(e)	(e)	(e)

Dose	0 NG/KG	Females 300 NG/KG	550 NG/KG	1000 NG/KG
All Organs Malignant Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	13/53 (25%)	16/53 (30%)	23/53 (43%)	33/53 (62%)
POLY-3 RATE (b)	13/35.14	16/40.41	23/46.99	33/43.01
POLY-3 PERCENT (g)	37.0%	39.6%	48.9%	76.7%
TERMINAL (d)	5/15 (33%)	6/16 (38%)	10/23 (44%)	6/7 (86%)
FIRST INCIDENCE	176	40	185	72
STATISTICAL TESTS				
LIFE TABLE	P<0.001 **	P=0.509	P=0.370	P<0.001 **
POLY 3	P<0.001 **	P=0.502	P=0.192	P<0.001 **
POLY 1.5	P<0.001 **	P=0.433	P=0.109	P<0.001 **
POLY 6	P<0.001 **	P=0.584	P=0.323	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	P=0.385	P=0.049 *	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	P=0.332	P=0.032 *	P<0.001 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 104 weeks

Dose	0 NG/KG	300 NG/KG	550 NG/KG	1000 NG/KG
		Females		
All Organs Malignant and Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	49/53 (92%)	49/53 (92%)	50/53 (94%)	49/53 (92%)
POLY-3 RATE (b)	49/49.21	49/50.28	50/51.09	49/50.22
POLY-3 PERCENT (g)	99.6%	97.5%	97.9%	97.6%
TERMINAL (d)	15/15 (100%)	15/16 (94%)	23/23 (100%)	7/7 (100%)
FIRST INCIDENCE	176	40	185	72
STATISTICAL TESTS				
LIFE TABLE	P=0.135	P=0.215N	P=0.012N*	P=0.175
POLY 3	P=0.355N	P=0.481N	P=0.576N	P=0.504N
POLY 1.5	P=0.345N	P=0.494N	P=0.541N	P=0.458N
POLY 6	P=0.506N	P=0.499N	P=0.896N	P=0.750N
LOGISTIC REGRESSION	P=0.461N	P=0.470N	P=0.299N	P=0.541N
COCH-ARM / FISHERS	P=0.540	P=0.642N	P=0.500	P=0.642N
ORDER RESTRICTED	P=0.280N	(e)	(e)	(e)

(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]
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

FINAL #2 RATS

Facility: Battelle Columbus Laboratory

Chemical CAS #: 57465-28-8

Lock Date: 01/09/01

Cage Range: All

Reasons For Removal:
25022 Accidently Killed
25019 Moribund Sacrifice
25021 Terminal Sacrifice
25018 Dosing Accident
25020 Natural Death

Removal Date Range: All

Treatment Groups:

Include 001	0 NG/KG	
Include 003	30 NG/KG	
Include 004	100	NG/KG
Include 005	175	NG/KG
Include 006	300	NG/KG
Include 007	550	NG/KG
Include 008	1000	NG/KG
Include 009	1000 NG/KG/STOP	

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]
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
DISPOSITION SUMMARY						
Animals Initially In Study	98	98	98	98	98	98
Early Deaths						
Moribund Sacrifice	25	18	21	19	27	18
Natural Death	10	9	6	11	9	12
Accidently Killed	1	3				
Dosing Accident	2			1	1	
Survivors						
Natural Death		1	1			
Terminal Sacrifice	15	24	25	22	16	23
Animals Examined Microscopically	53	55	53	53	53	53
ALIMENTARY SYSTEM						
Esophagus	(52)	(55)	(53)	(53)	(53)	(52)
Hemorrhage						1 [3.0]
Hyperplasia, Focal, Squamous			1 [1.0]			
Muscularis, Degeneration					1 [2.0]	
Muscularis, Inflammation	2 [1.0]	1 [1.0]		1 [1.0]	1 [1.0]	2 [1.5]
Periesophageal Tissue, Inflammation, Suppurative					1 [3.0]	
Intestine Large, Colon	(52)	(55)	(53)	(53)	(53)	(51)
Hyperplasia, Adenomatous			1 [3.0]			
Inflammation			1 [2.0]			
Parasite Metazoan		1	2	1		
Intestine Large, Rectum	(52)	(55)	(53)	(52)	(53)	(52)
Infiltration Cellular, Lymphocyte			1 [2.0]			
Inflammation, Chronic Active				1 [2.0]		
Mineralization		1 [2.0]				
Parasite Metazoan	2	2	3		1	
Artery, Inflammation, Chronic Active				1 [3.0]		
Intestine Large, Cecum	(52)	(54)	(53)	(51)	(53)	(52)
Edema		1 [2.0]				
Hyperplasia, Lymphoid					1 [2.0]	
Inflammation		1 [1.0]				
Intestine Small, Duodenum	(52)	(55)	(52)	(53)	(53)	(51)
Erosion	1 [2.0]					
Intestine Small, Ileum	(52)	(54)	(52)	(51)	(53)	(52)
Hyperplasia, Lymphoid					1 [2.0]	
Mineralization		1 [2.0]				
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]
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
ALIMENTARY SYSTEM - CONT						
Serosa, Inflammation, Chronic Active	1 [3.0]					
Liver	(53)	(55)	(53)	(53)	(53)	(51)
Angiectasis	3 [1.3]	8 [1.4]	4 [1.0]	1 [2.0]	1 [2.0]	2 [1.5]
Basophilic Focus	2	4	6	7	2	3
Basophilic Focus, Multiple	5	6	4	6	2	2
Cholangiofibrosis		1 [2.0]	1 [2.0]	1 [2.0]	3 [1.7]	13 [1.8]
Clear Cell Focus	1	1				
Clear Cell Focus, Multiple	1					
Cytoplasmic Alteration			1 [2.0]	1 [2.0]	1 [2.0]	1 [2.0]
Degeneration, Cystic					1 [1.0]	1 [2.0]
Eosinophilic Focus	6	4	7	4	2	3
Eosinophilic Focus, Multiple	5	6	6	17	15	21
Fatty Change, Diffuse	5 [1.2]	7 [1.0]	14 [1.4]	22 [1.1]	30 [1.1]	45 [1.4]
Fatty Change, Focal	2 [1.5]	6 [1.3]	8 [1.5]	6 [1.5]	3 [1.7]	2 [1.0]
Hematopoietic Cell Proliferation						1 [2.0]
Hepatocyte, Multinucleate		2 [1.0]	10 [1.1]	14 [1.0]	19 [1.3]	46 [1.5]
Hepatodiaphragmatic Nodule	1	1		1		
Hyperplasia, Nodular				1	3	26
Inflammation	36 [1.1]	40 [1.1]	49 [1.2]	50 [1.2]	51 [1.2]	51 [1.4]
Mixed Cell Focus	4	6	7	3		3
Mixed Cell Focus, Multiple	17	18	25	29	30	26
Necrosis	4 [2.3]	2 [2.0]	5 [1.6]	8 [2.1]	11 [1.9]	15 [2.0]
Pigmentation	1 [1.0]	11 [1.3]	41 [1.2]	39 [1.6]	48 [1.9]	51 [2.3]
Toxic Hepatopathy		6 [1.2]	22 [1.0]	27 [1.0]	39 [1.3]	51 [2.4]
Vacuolization Cytoplasmic		1 [1.0]				
Artery, Inflammation, Chronic Active				1 [2.0]	1 [2.0]	1 [2.0]
Bile Duct, Cyst	3 [1.7]	6 [2.3]		2 [2.0]	3 [2.7]	8 [2.0]
Bile Duct, Fibrosis	4 [1.0]	4 [1.5]	3 [1.3]	2 [1.0]	1 [1.0]	4 [1.0]
Bile Duct, Hyperplasia	3 [1.3]	7 [1.6]	7 [1.6]	13 [1.4]	14 [1.2]	45 [1.8]
Hepatocyte, Degeneration	3 [2.3]	1 [2.0]	1 [2.0]		1 [1.0]	1 [1.0]
Hepatocyte, Hypertrophy		23 [1.1]	32 [1.2]	36 [1.3]	42 [1.4]	50 [2.3]
Oval Cell, Hyperplasia		1 [1.0]	6 [1.2]	7 [1.1]	10 [1.2]	38 [1.8]
Portal, Fibrosis					2 [2.0]	1 [1.0]
Serosa, Inflammation		1 [2.0]				
Mesentery	(1)		(4)	(2)	(7)	(13)
Inflammation, Chronic Active	1 [4.0]					
Artery, Inflammation, Chronic Active			2 [3.0]	2 [3.5]	6 [3.2]	10 [2.6]
Fat, Necrosis			1 [3.0]		1 [3.0]	1 [3.0]
Oral Mucosa	(1)	(1)	(3)	(4)	(2)	(6)
Gingival, Hyperplasia, Squamous	1 [2.0]		2 [1.0]	2 [2.0]		4 [1.5]
Pancreas	(51)	(55)	(53)	(53)	(53)	(52)
Basophilic Focus		1		1		
Cyst						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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
ALIMENTARY SYSTEM - CONT						
Inflammation, Chronic Active	5 [1.6]	1 [1.0]	3 [2.0]	4 [1.3]	4 [1.8]	6 [2.3]
Acinus, Atrophy	5 [2.0]	3 [1.3]	2 [2.5]	7 [1.6]	2 [2.5]	11 [2.2]
Acinus, Hyperplasia		1 [2.0]	1 [3.0]	1 [2.0]	1 [2.0]	
Acinus, Vacuolization Cytoplasmic			1 [1.0]	4 [1.5]	9 [1.0]	20 [1.1]
Artery, Inflammation, Chronic Active		4 [2.0]	2 [3.0]	4 [2.5]	8 [2.5]	15 [2.5]
Artery, Mineralization		1 [2.0]				1 [2.0]
Duct, Hyperplasia						1 [4.0]
Duct, Inflammation, Chronic Active						2 [3.0]
Salivary Glands	(51)	(54)	(53)	(51)	(52)	(51)
Atrophy				1 [1.0]	1 [2.0]	
Cyst		1 [2.0]			1 [2.0]	
Inflammation, Acute					1 [1.0]	
Inflammation, Chronic Active	1 [2.0]				1 [2.0]	
Stomach, Forestomach	(52)	(55)	(53)	(53)	(53)	(51)
Edema	1 [3.0]		1 [2.0]		1 [2.0]	
Erosion		1 [1.0]				
Hyperkeratosis		3 [1.7]	1 [2.0]	1 [1.0]	3 [1.7]	1 [2.0]
Hyperplasia, Squamous	3 [1.7]	4 [2.0]	6 [1.8]	2 [2.0]	5 [1.8]	6 [1.7]
Inflammation, Acute	1 [1.0]					
Inflammation, Chronic Active		1 [3.0]	2 [2.0]	1 [2.0]	1 [2.0]	
Mineralization	1 [2.0]		1 [3.0]	1 [2.0]		1 [2.0]
Necrosis, Focal			1 [2.0]			
Ulcer	3 [2.0]	1 [2.0]		1 [2.0]	3 [2.3]	2 [2.0]
Stomach, Glandular	(51)	(53)	(53)	(53)	(53)	(51)
Erosion	1 [2.0]	1 [2.0]		1 [2.0]		
Metaplasia, Focal			1 [2.0]			
Mineralization	1 [2.0]	1 [3.0]		1 [1.0]		
Tooth	(12)	(12)	(10)	(9)	(10)	(9)
Peridontal Tissue, Inflammation, Chronic Active	2 [2.5]					1 [4.0]
Peridontal Tissue, Inflammation, Suppurative	10 [1.3]	12 [1.3]	10 [1.4]	9 [1.4]	10 [1.4]	8 [1.8]
CARDIOVASCULAR SYSTEM						
Blood Vessel	(53)	(55)	(53)	(53)	(53)	(53)
Aorta, Mineralization	3 [1.3]	1 [3.0]	1 [3.0]			2 [1.0]
Heart	(52)	(54)	(53)	(53)	(53)	(51)
Cardiomyopathy	9 [1.0]	16 [1.1]	17 [1.1]	16 [1.2]	24 [1.1]	28 [1.1]
Degeneration	1 [2.0]	1 [3.0]				1 [3.0]
Inflammation		1 [2.0]				
Mineralization	1 [2.0]	1 [2.0]				1 [2.0]
Thrombosis	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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
CARDIOVASCULAR SYSTEM - CONT						
Artery, Inflammation, Chronic Active				1 [2.0]		
Epicardium, Inflammation, Chronic Active					1 [3.0]	
Epicardium, Inflammation, Suppurative	2 [2.0]			1 [4.0]		
Myocardium, Inflammation					1 [3.0]	1 [1.0]
ENDOCRINE SYSTEM						
Adrenal Cortex	(52)	(55)	(53)	(53)	(53)	(52)
Angiectasis	11 [1.5]	13 [1.5]	25 [1.5]	19 [1.7]	20 [1.5]	8 [1.4]
Atrophy	1 [1.0]	3 [2.3]	5 [1.2]	3 [1.0]	5 [1.6]	19 [1.8]
Degeneration, Cystic	11 [2.1]	14 [2.4]	10 [2.0]	14 [2.8]	14 [2.1]	16 [2.3]
Hyperplasia	23 [1.9]	21 [2.4]	27 [2.1]	25 [2.0]	25 [2.4]	31 [2.7]
Hypertrophy	34 [1.9]	41 [2.0]	40 [1.9]	41 [2.1]	40 [1.9]	41 [2.0]
Inflammation, Suppurative			1 [1.0]			
Mineralization	1 [2.0]					1 [1.0]
Necrosis	1 [2.0]	1 [2.0]		1 [3.0]	1 [2.0]	1 [2.0]
Thrombosis						1 [2.0]
Vacuolization Cytoplasmic	5 [1.2]	3 [1.7]	5 [2.0]	2 [2.0]	9 [1.9]	4 [1.0]
Adrenal Medulla	(52)	(55)	(53)	(53)	(53)	(52)
Angiectasis			2 [2.0]	1 [2.0]	2 [2.5]	2 [2.5]
Hyperplasia	8 [1.5]	18 [2.0]	11 [1.7]	11 [2.0]	12 [1.8]	6 [2.0]
Necrosis				1 [3.0]		
Islets, Pancreatic	(52)	(54)	(53)	(53)	(53)	(52)
Hyperplasia	1 [2.0]	2 [2.0]	1 [1.0]	1 [1.0]		1 [1.0]
Parathyroid Gland	(47)	(50)	(48)	(46)	(49)	(47)
Hyperplasia		1 [2.0]	1 [2.0]	2 [1.5]	1 [3.0]	1 [1.0]
Pituitary Gland	(51)	(54)	(53)	(53)	(53)	(53)
Angiectasis	14 [2.1]	15 [2.1]	22 [2.2]	12 [2.3]	16 [2.3]	19 [2.3]
Cyst		3 [2.3]	1 [2.0]	1 [1.0]		2 [2.5]
Cytoplasmic Alteration		1 [2.0]	1 [2.0]	1 [2.0]	3 [2.0]	1 [2.0]
Inflammation, Focal, Granulomatous						1 [2.0]
Necrosis					1 [2.0]	
Pigmentation					1 [2.0]	
Vacuolization Cytoplasmic		1 [2.0]	1 [1.0]			
Pars Distalis, Hyperplasia	18 [1.9]	20 [2.5]	23 [2.2]	17 [2.1]	21 [1.9]	26 [2.2]
Thyroid Gland	(52)	(55)	(52)	(51)	(52)	(50)
Angiectasis		1 [2.0]	4 [2.0]			
Cyst				1 [2.0]		1 [2.0]
C-Cell, Hyperplasia	12 [1.9]	21 [1.7]	17 [1.5]	19 [1.8]	18 [1.9]	16 [1.9]
Follicle, Cyst			1 [2.0]			
Follicular Cell, Hyperplasia			1 [1.0]	1 [1.0]		
Follicular Cell, Hypertrophy	9 [1.3]	13 [1.2]	13 [1.5]	17 [1.1]	28 [1.5]	26 [1.3]

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]
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(50)	(55)	(52)	(50)	(53)	(52)
Hyperplasia		1 [2.0]				
Hyperplasia, Squamous			1 [1.0]			
Inflammation	28 [1.5]	36 [1.4]	39 [1.7]	28 [1.6]	30 [1.4]	27 [1.3]
Duct, Cyst	29 [1.9]	32 [2.0]	34 [2.0]	37 [1.9]	39 [2.0]	42 [2.2]
Ovary	(52)	(54)	(53)	(52)	(52)	(52)
Atrophy	45 [4.0]	49 [4.0]	46 [4.0]	45 [4.0]	47 [4.0]	46 [4.0]
Cyst	12 [2.0]	17 [2.2]	17 [2.4]	15 [2.3]	16 [2.1]	18 [2.1]
Inflammation, Chronic Active				1 [2.0]	1 [3.0]	
Inflammation, Suppurative		1 [1.0]				2 [2.5]
Necrosis					1 [4.0]	
Artery, Inflammation, Chronic Active			1 [3.0]	1 [2.0]		
Oviduct	(1)	(1)			(1)	(3)
Cyst						1 [4.0]
Inflammation, Chronic Active					1 [3.0]	
Inflammation, Suppurative	1 [2.0]	1 [1.0]				2 [2.5]
Uterus	(52)	(55)	(53)	(52)	(53)	(52)
Adenomyosis		1 [2.0]		1 [4.0]		2 [2.5]
Cyst		1 [3.0]				
Erosion			1 [2.0]			
Hemorrhage				1 [2.0]	2 [3.0]	1 [3.0]
Inflammation, Chronic Active				2 [3.0]	1 [4.0]	1 [2.0]
Inflammation, Granulomatous	1 [2.0]					
Inflammation, Suppurative	12 [1.8]	12 [1.8]	11 [1.6]	16 [2.0]	10 [1.6]	6 [2.2]
Metaplasia, Squamous	26 [1.6]	33 [1.9]	25 [2.1]	28 [2.3]	29 [1.8]	27 [2.2]
Thrombosis				1 [2.0]		1 [3.0]
Ulcer		1 [2.0]				
Vacuolization Cytoplasmic			2 [2.0]			
Artery, Inflammation, Chronic Active			1 [3.0]			1 [3.0]
Cervix, Cyst					1 [2.0]	
Cervix, Hyperplasia, Stromal						1 [3.0]
Endometrium, Hyperplasia, Cystic	23 [1.7]	33 [2.1]	28 [1.8]	24 [2.5]	26 [2.0]	32 [2.2]
Epithelium, Hyperplasia	1 [3.0]			1 [3.0]		
Epithelium, Necrosis			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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(55)	(53)	(53)	(53)	(53)
Angiectasis						1 [2.0]
Fibrosis			1 [3.0]			
Hyperplasia	47 [3.4]	37 [3.2]	35 [3.3]	44 [3.3]	45 [3.2]	46 [3.2]
Lymph Node	(2)	(6)	(6)	(6)	(4)	(7)
Ectasia				1 [2.0]		
Deep Cervical, Ectasia			1 [2.0]			
Inguinal, Hyperplasia, Plasma Cell			1 [2.0]			
Inguinal, Pigmentation			1 [2.0]			
Lumbar, Ectasia						2 [2.0]
Lumbar, Hyperplasia						1 [2.0]
Lumbar, Hyperplasia, Lymphoid		1 [2.0]				
Lumbar, Hyperplasia, Plasma Cell				2 [2.5]	1 [3.0]	
Mediastinal, Ectasia		2 [1.5]	3 [2.0]			
Mediastinal, Hemorrhage			2 [2.0]	1 [2.0]	1 [2.0]	
Mediastinal, Hyperplasia, Lymphoid					1 [3.0]	
Mediastinal, Hyperplasia, Plasma Cell					1 [2.0]	1 [3.0]
Mediastinal, Inflammation, Suppurative					1 [2.0]	
Pancreatic, Hyperplasia, Plasma Cell						1 [2.0]
Lymph Node, Mandibular	(52)	(53)	(51)	(51)	(52)	(51)
Ectasia	1 [2.0]	1 [3.0]	4 [2.0]	4 [2.5]	4 [2.0]	4 [2.5]
Hemorrhage					1 [2.0]	
Hyperplasia, Lymphoid		1 [2.0]	1 [2.0]	1 [2.0]	2 [2.0]	
Hyperplasia, Plasma Cell	18 [2.2]	24 [2.0]	31 [2.2]	21 [2.3]	29 [2.0]	11 [2.2]
Lymph Node, Mesenteric	(52)	(54)	(52)	(52)	(53)	(51)
Atrophy			1 [3.0]			
Ectasia	1 [2.0]					1 [2.0]
Hemorrhage	2 [2.0]	3 [2.0]		1 [2.0]	1 [2.0]	
Hyperplasia, Histiocytic	3 [1.7]					1 [2.0]
Hyperplasia, Plasma Cell					1 [2.0]	
Pigmentation						1 [1.0]
Spleen	(52)	(55)	(52)	(53)	(53)	(52)
Hematopoietic Cell Proliferation	39 [1.7]	43 [1.6]	46 [1.4]	45 [1.5]	41 [1.7]	42 [1.4]
Hyperplasia, Lymphoid			1 [2.0]		1 [2.0]	1 [3.0]
Necrosis		1 [2.0]				
Pigmentation	49 [1.3]	50 [1.4]	51 [1.5]	51 [1.4]	52 [1.5]	52 [1.5]
Lymphoid Follicle, Atrophy		5 [2.6]	3 [2.0]	2 [1.5]	5 [2.0]	3 [2.3]
Red Pulp, Atrophy			4 [2.0]	1 [2.0]	1 [2.0]	
Thymus	(50)	(52)	(46)	(48)	(41)	(49)
Atrophy	37 [2.5]	34 [2.6]	41 [2.8]	45 [2.8]	36 [3.3]	47 [3.5]
Fibrosis			1 [2.0]			
Hemorrhage	1 [3.0]	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]
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
HEMATOPOIETIC SYSTEM - CONT						
Inflammation	1 [3.0]			1 [3.0]		
INTEGUMENTARY SYSTEM						
Mammary Gland	(52)	(55)	(53)	(53)	(53)	(52)
Cyst	8 [1.8]	3 [1.7]	1 [4.0]	4 [3.3]	5 [2.6]	1 [2.0]
Fibrosis, Focal					1 [2.0]	
Hyperplasia	32 [1.4]	33 [1.4]	30 [1.4]	29 [1.2]	21 [1.2]	23 [1.1]
Inflammation, Chronic Active	1 [3.0]			2 [3.0]	2 [2.0]	
Inflammation, Granulomatous	2 [2.0]	2 [3.0]		1 [2.0]		
Skin	(52)	(55)	(53)	(53)	(53)	(53)
Cyst, Squamous	1 [2.0]	1 [3.0]				
Ulcer			1 [2.0]			
Dermis, Inflammation, Focal	1 [2.0]					
Subcutaneous Tissue, Inflammation, Suppurative				1 [2.0]		
MUSCULOSKELETAL SYSTEM						
Bone	(53)	(55)	(53)	(53)	(53)	(53)
Inflammation, Chronic Active	1 [2.0]					
Osteopetrosis			1 [2.0]		2 [2.0]	
Cartilage, Hypertrophy, Focal						1 [2.0]
Skeletal Muscle	(1)	(1)	(1)			
Inflammation, Chronic Active	1 [3.0]					
NERVOUS SYSTEM						
Brain	(53)	(55)	(53)	(53)	(53)	(53)
Hemorrhage						1 [3.0]
Hydrocephalus	1 [1.0]		2 [2.0]			1 [2.0]
RESPIRATORY SYSTEM						
Lung	(53)	(55)	(53)	(53)	(53)	(51)
Congestion	1 [3.0]	1 [2.0]			1 [2.0]	
Infiltration Cellular, Histiocyte	41 [1.7]	49 [1.7]	45 [1.7]	48 [1.6]	45 [1.6]	49 [1.7]
Inflammation, Chronic Active	5 [1.4]	3 [1.3]		1 [2.0]	1 [2.0]	
Inflammation, Granulomatous	3 [1.7]		2 [1.5]			

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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
RESPIRATORY SYSTEM - CONT						
Inflammation, Suppurative						1 [2.0]
Metaplasia, Squamous	1 [2.0]		1 [2.0]	2 [1.5]	3 [2.3]	9 [1.7]
Mineralization		1 [3.0]	1 [3.0]			1 [2.0]
Thrombosis		2 [2.5]				1 [2.0]
Alveolar Epithelium, Hyperplasia	12 [1.1]	1 [1.0]		1 [3.0]	2 [1.0]	
Alveolar Epithelium, Metaplasia, Bronchiolar		29 [1.3]	34 [1.6]	41 [1.8]	39 [1.7]	47 [2.1]
Serosa, Fibrosis			2 [1.5]			
Serosa, Inflammation, Chronic Active		1 [2.0]				
Serosa, Inflammation, Suppurative	2 [2.5]			1 [3.0]	1 [3.0]	
Vein, Thrombosis				1 [3.0]		
Nose	(53)	(54)	(52)	(53)	(52)	(53)
Nasolacrimal Duct, Inflammation		1 [2.0]		1 [2.0]	1 [2.0]	
Nasolacrimal Duct, Glands, Hyperplasia						1 [4.0]
Nasolacrimal Duct, Respiratory Epithelium, Hyperplasia					1 [2.0]	
Nasopharyngeal Duct, Inflammation, Suppurative	1 [4.0]		1 [3.0]			
Olfactory Epithelium, Inflammation, Suppurative	1 [3.0]		1 [3.0]			
Respiratory Epithelium, Hyperplasia	2 [2.5]		1 [2.0]	1 [2.0]	2 [2.0]	2 [2.5]
Respiratory Epithelium, Inflammation, Suppurative			1 [3.0]		1 [2.0]	1 [3.0]
Respiratory Epithelium, Metaplasia	1 [4.0]				1 [2.0]	
Turbinate, Cyst						1 [1.0]
Turbinate, Inflammation, Suppurative	2 [2.0]		1 [2.0]	1 [1.0]	2 [2.5]	
Trachea	(53)	(55)	(53)	(53)	(53)	(52)
Inflammation	1 [2.0]					
Peritracheal Tissue, Inflammation	1 [3.0]					
SPECIAL SENSES SYSTEM						
Ear					(1)	
Inflammation					1 [1.0]	
Eye	(51)	(55)	(53)	(53)	(53)	(52)
Atrophy			1 [3.0]	1 [3.0]		
Cataract					1 [3.0]	1 [3.0]
Edema					1 [3.0]	
Anterior Chamber, Inflammation, Suppurative						1 [3.0]
Anterior Chamber, Ciliary Body, Cornea, Inflammation, Suppurative			1 [2.0]			
Cornea, Inflammation, Suppurative						1 [3.0]
Retina, Atrophy			3 [2.3]	1 [3.0]		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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	30 NG/KG	100 NG/KG	175 NG/KG	300 NG/KG	550 NG/KG
SPECIAL SENSES SYSTEM - CONT						
Retina, Degeneration						1 [2.0]
Harderian Gland	(53)	(53)	(53)	(53)	(53)	(52)
Inflammation	2 [1.0]	3 [1.0]	6 [1.2]	6 [1.2]	3 [1.0]	3 [1.0]
URINARY SYSTEM						
Kidney	(53)	(55)	(53)	(53)	(53)	(52)
Calculus Micro Observation Only			1	1		1
Casts Protein	4 [1.3]	3 [1.3]	1 [1.0]	6 [1.2]		
Cyst				2 [1.5]		
Inflammation, Chronic Active	2 [2.0]	2 [2.0]	1 [3.0]	1 [3.0]	1 [1.0]	1 [2.0]
Inflammation, Suppurative			3 [1.0]			1 [3.0]
Mineralization	32 [1.0]	39 [1.0]	44 [1.0]	44 [1.0]	44 [1.0]	39 [1.1]
Necrosis			1 [2.0]		1 [3.0]	1 [3.0]
Nephropathy	32 [1.3]	29 [1.3]	38 [1.5]	35 [1.3]	38 [1.5]	42 [2.1]
Papilla, Angiectasis					1 [2.0]	
Pelvis, Dilatation	2 [2.0]	1 [3.0]				1 [2.0]
Pelvis, Inflammation, Chronic Active		2 [2.5]	2 [2.5]	2 [2.5]		
Pelvis, Inflammation, Suppurative	2 [1.0]				3 [2.0]	
Renal Tubule, Accumulation, Hyaline Droplet		1 [3.0]				
Renal Tubule, Dilatation				1 [2.0]		
Transitional Epithelium, Hyperplasia	4 [2.0]	2 [2.5]	8 [1.9]	4 [2.5]	8 [1.6]	8 [2.3]
Ureter			(1)			
Mineralization			1 [3.0]			
Transitional Epithelium, Hyperplasia			1 [2.0]			
Urinary Bladder	(51)	(54)	(53)	(52)	(52)	(52)
Edema				1 [3.0]		
Hemorrhage				1 [2.0]		
Inflammation	4 [1.5]	6 [1.5]	10 [1.4]	6 [2.2]	7 [1.6]	4 [1.0]
Transitional Epithelium, Hyperplasia	1 [2.0]	1 [3.0]	1 [2.0]	2 [2.5]	1 [3.0]	2 [2.5]

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]
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
DISPOSITION SUMMARY		
Animals Initially In Study	98	50
Early Deaths		
Natural Death	12	6
Moribund Sacrifice	34	15
Dosing Accident		1
Survivors		
Terminal Sacrifice	7	28
Animals Examined Microscopically	53	50
ALIMENTARY SYSTEM		
Esophagus	(52)	(50)
Cyst	1 [2.0]	
Muscularis, Inflammation		1 [1.0]
Intestine Large, Colon	(53)	(50)
Parasite Metazoan	1	
Intestine Large, Rectum	(53)	(50)
Parasite Metazoan	1	1
Intestine Small, Duodenum	(53)	(50)
Erosion	2 [1.5]	
Ulcer	1 [3.0]	
Epithelium, Hyperplasia	1 [2.0]	
Intestine Small, Jejunum	(53)	(50)
Hyperplasia, Lymphoid	1 [2.0]	
Liver	(53)	(50)
Angiectasis	2 [2.0]	8 [1.5]
Basophilic Focus	2	7
Basophilic Focus, Multiple	3	9
Cholangiofibrosis	22 [2.3]	1 [1.0]
Clear Cell Focus		1
Clear Cell Focus, Multiple		4
Cytoplasmic Alteration	1 [3.0]	
Degeneration, Cystic	2 [2.0]	3 [2.0]
Eosinophilic Focus	6	3
Eosinophilic Focus, Multiple	11	9
Fatty Change, Diffuse	47 [1.8]	12 [1.3]
Fatty Change, Focal		11 [1.5]
Hepatocyte, Multinucleate	49 [1.7]	20 [1.0]
Hepatodiaphragmatic Nodule	1	1
Hyperplasia, Nodular	40	

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SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
ALIMENTARY SYSTEM - CONT		
Inflammation	51 [1.2]	46 [1.2]
Mixed Cell Focus	4	1
Mixed Cell Focus, Multiple	5	35
Multinucleated		1 [1.0]
Necrosis	17 [2.2]	4 [2.8]
Pigmentation	48 [2.5]	48 [1.8]
Toxic Hepatopathy	49 [3.4]	15 [1.2]
Bile Duct, Cyst	12 [2.0]	5 [2.2]
Bile Duct, Fibrosis	5 [1.2]	4 [1.0]
Bile Duct, Hyperplasia	45 [2.5]	16 [1.4]
Bile Duct, Inflammation	1 [2.0]	
Hepatocyte, Degeneration	7 [2.3]	
Hepatocyte, Hypertrophy	49 [3.4]	21 [1.4]
Oval Cell, Hyperplasia	40 [2.2]	1 [1.0]
Portal, Fibrosis	10 [2.1]	
Serosa, Inflammation	1 [1.0]	
Mesentery	(11)	
Inflammation, Chronic Active	3 [2.7]	
Artery, Inflammation, Chronic Active	7 [2.7]	
Fat, Necrosis	1 [2.0]	
Oral Mucosa	(11)	(6)
Gingival, Cyst, Squamous	1 [2.0]	
Gingival, Hyperplasia, Squamous	3 [2.7]	3 [2.3]
Pharyngeal, Hyperplasia, Squamous		1 [4.0]
Pancreas	(51)	(48)
Basophilic Focus		1
Cyst	1 [2.0]	
Inflammation, Chronic Active	13 [2.2]	4 [1.5]
Necrosis	1 [2.0]	
Acinus, Atrophy	18 [2.1]	7 [1.4]
Acinus, Vacuolization Cytoplasmic	23 [1.4]	1 [1.0]
Artery, Inflammation, Chronic Active	11 [2.9]	1 [2.0]
Duct, Dilatation	2 [4.0]	
Duct, Hyperplasia	1 [2.0]	
Salivary Glands	(51)	(49)
Atrophy		1 [2.0]
Cyst		2 [3.0]
Inflammation, Acute	1 [2.0]	
Stomach, Forestomach	(53)	(50)
Edema		2 [2.0]
Hyperkeratosis	2 [1.5]	
Hyperplasia, Squamous	8 [1.9]	2 [1.5]
Mineralization	2 [2.0]	

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INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
ALIMENTARY SYSTEM - CONT		
Ulcer	2 [2.0]	
Stomach, Glandular	(53)	(50)
Erosion		1 [2.0]
Inflammation, Chronic Active	1 [1.0]	
Mineralization	1 [2.0]	
Artery, Inflammation, Chronic Active	1 [2.0]	
Glands, Ectasia	1 [2.0]	
Glands, Hyperplasia	1 [2.0]	
Tooth	(19)	(12)
Peridontal Tissue, Fibrosis	1 [3.0]	1 [3.0]
Peridontal Tissue, Inflammation, Suppurative	18 [1.6]	11 [1.6]
CARDIOVASCULAR SYSTEM		
Blood Vessel	(53)	(50)
Aorta, Mineralization		1 [2.0]
Heart	(51)	(50)
Cardiomyopathy	32 [1.2]	15 [1.2]
Mineralization		1 [2.0]
Thrombosis	1 [3.0]	1 [2.0]
Artery, Inflammation, Chronic Active		1 [1.0]
Endocardium, Myocardium, Inflammation, Acute	1 [3.0]	
Epicardium, Inflammation, Chronic Active	1 [2.0]	
Epicardium, Inflammation, Suppurative		1 [4.0]
ENDOCRINE SYSTEM		
Adrenal Cortex	(53)	(50)
Angiectasis	1 [2.0]	14 [1.7]
Atrophy	30 [2.2]	9 [1.7]
Degeneration, Cystic	10 [2.2]	20 [2.4]
Hyperplasia	24 [2.5]	26 [2.0]
Hypertrophy	41 [1.8]	42 [2.4]
Inflammation, Suppurative		1 [2.0]
Mineralization	1 [2.0]	
Necrosis	2 [1.5]	2 [1.5]
Vacuolization Cytoplasmic	17 [1.9]	6 [1.5]
Adrenal Medulla	(53)	(50)
Hyperplasia	1 [2.0]	9 [1.4]
Parathyroid Gland	(46)	(44)
Cyst		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)

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
ENDOCRINE SYSTEM - CONT		
Hyperplasia		2 [1.5]
Pituitary Gland	(53)	(48)
Angiectasis	9 [2.1]	14 [2.3]
Cyst	1 [1.0]	1 [3.0]
Cytoplasmic Alteration		1 [2.0]
Pars Distalis, Hyperplasia	17 [1.9]	17 [2.0]
Thyroid Gland	(48)	(47)
Angiectasis		1 [2.0]
Atrophy	1 [4.0]	
Infiltration Cellular, Lymphocyte	1 [2.0]	
C-Cell, Hyperplasia	19 [1.7]	18 [1.8]
Follicular Cell, Hyperplasia	1 [4.0]	
Follicular Cell, Hypertrophy	16 [1.3]	22 [1.4]
GENERAL BODY SYSTEM		
None		
GENITAL SYSTEM		
Clitoral Gland	(51)	(48)
Inflammation	22 [1.3]	32 [1.6]
Duct, Cyst	45 [2.3]	39 [1.9]
Ovary	(53)	(50)
Atrophy	33 [3.9]	47 [4.0]
Cyst	11 [2.5]	17 [2.3]
Oviduct	(1)	(2)
Inflammation, Suppurative	1 [3.0]	2 [3.0]
Uterus	(53)	(50)
Hemorrhage	1 [2.0]	
Inflammation, Chronic Active		1 [4.0]
Inflammation, Suppurative	4 [2.5]	11 [2.2]
Metaplasia, Squamous	11 [2.4]	28 [2.0]
Endometrium, Hyperplasia, Cystic	9 [1.8]	31 [2.0]
Epithelium, Hyperplasia		1 [2.0]
Vagina	(1)	
Cyst	1 [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)

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
HEMATOPOIETIC SYSTEM - CONT		
Bone Marrow	(53)	(50)
Atrophy	1 [3.0]	
Hyperplasia	46 [3.3]	34 [3.1]
Lymph Node	(12)	(2)
Iliac, Ectasia		1 [2.0]
Mediastinal, Angiectasis	1 [2.0]	
Mediastinal, Ectasia	5 [1.8]	
Mediastinal, Hemorrhage	6 [2.0]	
Mediastinal, Hyperplasia, Lymphoid	1 [2.0]	
Mediastinal, Pigmentation	2 [2.0]	
Pancreatic, Hemorrhage	1 [1.0]	
Lymph Node, Mandibular	(51)	(49)
Atrophy	1 [3.0]	
Ectasia	3 [2.3]	3 [2.3]
Hemorrhage	1 [2.0]	
Hyperplasia, Lymphoid	1 [2.0]	
Hyperplasia, Plasma Cell	15 [2.1]	21 [2.3]
Lymph Node, Mesenteric	(53)	(50)
Atrophy	1 [3.0]	2 [1.5]
Ectasia	1 [2.0]	
Hemorrhage	2 [1.5]	
Hyperplasia, Histiocytic	1 [2.0]	1 [2.0]
Hyperplasia, Lymphoid	2 [2.0]	
Hyperplasia, Plasma Cell		1 [2.0]
Spleen	(52)	(50)
Hematopoietic Cell Proliferation	37 [1.6]	37 [1.5]
Hyperplasia, Lymphoid	3 [2.0]	
Pigmentation	50 [1.3]	50 [1.6]
Lymphoid Follicle, Atrophy	6 [2.3]	4 [2.5]
Red Pulp, Atrophy	2 [2.5]	
Thymus	(44)	(43)
Atrophy	41 [3.5]	39 [3.0]
INTEGUMENTARY SYSTEM		
Mammary Gland	(53)	(50)
Cyst	1 [3.0]	13 [2.7]
Hyperplasia	9 [1.4]	22 [1.1]
Skin	(53)	(50)
Cyst, Squamous	1 [3.0]	2 [2.5]

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)

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
MUSCULOSKELETAL SYSTEM		
Skeletal Muscle	(1)	
Inflammation, Chronic Active	1 [2.0]	
NERVOUS SYSTEM		
Brain	(53)	(50)
Hemorrhage	1 [2.0]	
Inflammation, Focal, Suppurative	1 [3.0]	
Necrosis, Focal	1 [3.0]	
RESPIRATORY SYSTEM		
Lung	(51)	(50)
Hemorrhage	1 [2.0]	1 [2.0]
Infiltration Cellular, Histiocyte	42 [1.5]	42 [1.5]
Inflammation, Chronic Active	2 [2.5]	
Metaplasia, Squamous	4 [1.8]	
Mineralization	1 [2.0]	1 [2.0]
Alveolar Epithelium, Metaplasia, Bronchiolar	40 [1.9]	32 [1.5]
Serosa, Inflammation, Suppurative		1 [3.0]
Nose	(53)	(50)
Goblet Cell, Respiratory Epithelium, Hyperplasia	1 [2.0]	
Nasolacrimal Duct, Inflammation	1 [3.0]	1 [3.0]
Nasolacrimal Duct, Respiratory Epithelium, Hyperplasia	1 [3.0]	
Nasopharyngeal Duct, Respiratory Epithelium, Hyperplasia	1 [3.0]	
Respiratory Epithelium, Hyperplasia	1 [2.0]	1 [2.0]
Turbinate, Cyst	1 [2.0]	
Turbinate, Inflammation, Suppurative	4 [2.3]	1 [1.0]
Vomeronasal Organ, Vacuolization Cytoplasmic	1 [2.0]	
SPECIAL SENSES SYSTEM		
Eye	(52)	(50)
Anterior Chamber, Inflammation, Suppurative	1 [3.0]	1 [3.0]
Cornea, Inflammation, Suppurative	2 [2.5]	1 [3.0]
Optic Nerve, Degeneration	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]
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB-126)

SPRAGUE-DAWLEY RATS FEMALE	1000 NG/KG	1000 NG/ KG/STOP
SPECIAL SENSES SYSTEM - CONT		
Retina, Atrophy	4 [2.5]	
Harderian Gland	(52)	(50)
Inflammation	6 [1.2]	9 [1.1]
URINARY SYSTEM		
Kidney	(53)	(50)
Casts Protein	2 [1.5]	3 [1.7]
Inflammation, Suppurative	2 [2.0]	
Mineralization	37 [1.0]	45 [1.0]
Necrosis	1 [3.0]	
Nephropathy	47 [2.1]	38 [1.4]
Papilla, Necrosis	1 [2.0]	
Pelvis, Dilatation	2 [3.5]	1 [2.0]
Pelvis, Hemorrhage	1 [3.0]	
Pelvis, Inflammation, Chronic Active	1 [3.0]	1 [3.0]
Pelvis, Metaplasia, Squamous	1 [2.0]	
Transitional Epithelium, Hyperplasia	11 [2.0]	2 [2.0]
Ureter	(3)	
Inflammation	1 [2.0]	
Metaplasia, Squamous	2 [2.5]	
Mineralization	2 [3.5]	
Transitional Epithelium, Hyperplasia	3 [3.0]	
Urinary Bladder	(53)	(50)
Inflammation	6 [1.5]	3 [1.3]
Metaplasia, Squamous	1 [2.0]	
Transitional Epithelium, Hyperplasia	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)

END OF REPORT

National Toxicology Program

TR-529 Toxic Equivalency Factor Evaluation (PCB 153)

Revised Pathology Tables – Female Rats Core Study

- **P03 - Incidence Rates of Non-Neoplastic Lesions**
- **P05 - Incidence Rates of Neoplasms by Anatomic Site (systemic lesions abridged)**
- **P08 - Statistical Analysis of Primary Tumors (control vs stop group)**
- **P08 - Statistical Analysis of Primary Tumors (control vs treated group)**
- **P18 - Incidence Rates of Non-Neoplastic Lesions**

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB 153)

FINAL#2

Facility: Battelle Columbus Laboratory

Chemical CAS #: 35065-27-1

Lock Date: 01/16/02

Cage Range: All

Reasons For Removal: 25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

Removal Date Range: All

Treatment Groups: Include All

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

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
DISPOSITION SUMMARY						
Animals Initially In Study	98	86	98	98	98	80
Early Deaths						
Natural Death	11	15	8	9	15	11
Moribund Sacrifice	18	23	17	22	18	19
Dosing Accident				1		
Survivors						
Terminal Sacrifice	24	16	28	20	20	21
Natural Death				1		
Animals Examined Microscopically	53	54	53	53	53	51
ALIMENTARY SYSTEM						
Esophagus	(53)	(54)	(53)	(53)	(53)	(51)
Muscularis, Inflammation		3 (6%)		1 (2%)	2 (4%)	1 (2%)
Periesophageal Tissue, Hemorrhage				1 (2%)		
Periesophageal Tissue, Inflammation				1 (2%)		
Intestine Large, Colon	(53)	(54)	(53)	(53)	(53)	(50)
Inflammation, Chronic Active						1 (2%)
Parasite Metazoan		1 (2%)	1 (2%)		1 (2%)	2 (4%)
Intestine Large, Rectum	(53)	(54)	(53)	(53)	(53)	(50)
Inflammation, Chronic Active						1 (2%)
Parasite Metazoan	1 (2%)	2 (4%)	3 (6%)	7 (13%)	5 (9%)	5 (10%)
Intestine Large, Cecum	(53)	(54)	(53)	(53)	(53)	(50)
Inflammation, Chronic Active						1 (2%)
Intestine Small, Duodenum	(53)	(54)	(53)	(53)	(53)	(51)
Parasite Metazoan						1 (2%)
Intestine Small, Jejunum	(53)	(54)	(53)	(53)	(53)	(50)
Peyer's Patch, Hyperplasia, Lymphoid	1 (2%)					1 (2%)
Intestine Small, Ileum	(52)	(54)	(53)	(53)	(53)	(50)
Hyperplasia, Lymphoid	1 (2%)					
Liver	(53)	(54)	(53)	(53)	(53)	(51)
Angiectasis	5 (9%)	2 (4%)	2 (4%)	1 (2%)	8 (15%)	4 (8%)
Basophilic Focus	8 (15%)	5 (9%)	16 (30%)	6 (11%)	3 (6%)	8 (16%)
Basophilic Focus, Multiple	8 (15%)	12 (22%)	9 (17%)	7 (13%)	7 (13%)	2 (4%)
Cholangiofibrosis					1 (2%)	
Clear Cell Focus	3 (6%)	3 (6%)	4 (8%)			2 (4%)
Clear Cell Focus, Multiple	3 (6%)	2 (4%)	1 (2%)			
Eosinophilic Focus	5 (9%)	1 (2%)	8 (15%)	7 (13%)	14 (26%)	6 (12%)
Eosinophilic Focus, Multiple	7 (13%)	1 (2%)	8 (15%)	12 (23%)	9 (17%)	12 (24%)
Fatty Change, Diffuse	3 (6%)	7 (13%)	2 (4%)	11 (21%)	21 (40%)	17 (33%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
ALIMENTARY SYSTEM - CONT						
Fatty Change, Focal	4 (8%)		3 (6%)	5 (9%)	4 (8%)	1 (2%)
Hematopoietic Cell Proliferation	20 (38%)	22 (41%)	13 (25%)	18 (34%)	16 (30%)	14 (27%)
Hepatodiaphragmatic Nodule					1 (2%)	1 (2%)
Hyperplasia, Nodular					1 (2%)	1 (2%)
Inflammation	44 (83%)	39 (72%)	44 (83%)	47 (89%)	48 (91%)	45 (88%)
Mixed Cell Focus	8 (15%)	3 (6%)	7 (13%)	6 (11%)	5 (9%)	3 (6%)
Mixed Cell Focus, Multiple	21 (40%)	16 (30%)	22 (42%)	19 (36%)	19 (36%)	12 (24%)
Necrosis	7 (13%)	7 (13%)	7 (13%)	5 (9%)	12 (23%)	10 (20%)
Pigmentation	1 (2%)	1 (2%)	2 (4%)	5 (9%)	5 (9%)	9 (18%)
Bile Duct, Cyst	3 (6%)	2 (4%)	2 (4%)	3 (6%)	5 (9%)	2 (4%)
Bile Duct, Fibrosis	2 (4%)	1 (2%)	2 (4%)	2 (4%)	2 (4%)	3 (6%)
Bile Duct, Hyperplasia	5 (9%)	3 (6%)	2 (4%)	14 (26%)	10 (19%)	17 (33%)
Centrilobular, Degeneration	2 (4%)	10 (19%)	4 (8%)	2 (4%)	2 (4%)	5 (10%)
Hepatocyte, Hypertrophy		5 (9%)	5 (9%)	24 (45%)	39 (74%)	41 (80%)
Oval Cell, Hyperplasia				1 (2%)		4 (8%)
Serosa, Fibrosis						1 (2%)
Serosa, Inflammation			2 (4%)			
Mesentery			(1)		(1)	
Fat, Inflammation, Chronic Active			1 (100%)			
Oral Mucosa	(21)	(12)	(16)	(12)	(16)	(25)
Gingival, Hyperplasia, Squamous	21 (100%)	10 (83%)	16 (100%)	11 (92%)	16 (100%)	25 (100%)
Pancreas	(53)	(54)	(53)	(53)	(53)	(51)
Cyst			1 (2%)			
Degeneration		1 (2%)				
Inflammation, Chronic Active	2 (4%)		1 (2%)	1 (2%)		2 (4%)
Acinus, Atrophy	1 (2%)		1 (2%)	1 (2%)		2 (4%)
Acinus, Hyperplasia	3 (6%)					
Acinus, Vacuolization Cytoplasmic				1 (2%)	1 (2%)	2 (4%)
Salivary Glands	(51)	(52)	(53)	(52)	(53)	(51)
Ectopic Tissue				1 (2%)		
Stomach, Forestomach	(53)	(54)	(53)	(53)	(53)	(51)
Hyperkeratosis		1 (2%)			1 (2%)	2 (4%)
Hyperplasia, Squamous	3 (6%)	4 (7%)	2 (4%)	6 (11%)	4 (8%)	4 (8%)
Inflammation				3 (6%)	3 (6%)	2 (4%)
Mineralization		1 (2%)		2 (4%)	2 (4%)	
Ulcer				2 (4%)	3 (6%)	1 (2%)
Serosa, Inflammation, Chronic Active			1 (2%)			
Stomach, Glandular	(53)	(54)	(53)	(53)	(53)	(51)
Erosion	1 (2%)		1 (2%)	2 (4%)		
Inflammation				2 (4%)		
Mineralization	5 (9%)	8 (15%)	8 (15%)	10 (19%)	10 (19%)	2 (4%)
Tooth	(34)	(13)	(19)	(22)	(23)	(35)
Degeneration	1 (3%)					

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

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
ALIMENTARY SYSTEM - CONT						
Peridontal Tissue, Inflammation	33 (97%)	13 (100%)	19 (100%)	21 (95%)	23 (100%)	35 (100%)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(52)	(54)	(53)	(53)	(53)	(51)
Aorta, Mineralization	2 (4%)	1 (2%)		1 (2%)	1 (2%)	
Heart	(52)	(54)	(53)	(53)	(53)	(51)
Cardiomyopathy	22 (42%)	18 (33%)	19 (36%)	19 (36%)	23 (43%)	24 (47%)
Inflammation		2 (4%)		1 (2%)		1 (2%)
Mineralization	1 (2%)			1 (2%)		
Necrosis		1 (2%)				
Thrombosis		2 (4%)				
ENDOCRINE SYSTEM						
Adrenal Cortex	(53)	(54)	(53)	(53)	(53)	(51)
Angiectasis	21 (40%)	23 (43%)	34 (64%)	25 (47%)	29 (55%)	21 (41%)
Atrophy				1 (2%)	2 (4%)	
Degeneration, Cystic	9 (17%)	12 (22%)	15 (28%)	13 (25%)	12 (23%)	13 (25%)
Hematopoietic Cell Proliferation		1 (2%)		1 (2%)		3 (6%)
Hyperplasia	18 (34%)	24 (44%)	27 (51%)	27 (51%)	28 (53%)	11 (22%)
Hypertrophy	48 (91%)	35 (65%)	45 (85%)	35 (66%)	42 (79%)	41 (80%)
Inflammation				1 (2%)		1 (2%)
Mineralization				2 (4%)	1 (2%)	
Necrosis	1 (2%)	2 (4%)	1 (2%)	2 (4%)	3 (6%)	3 (6%)
Vacuolization Cytoplasmic	10 (19%)	8 (15%)	14 (26%)	16 (30%)	12 (23%)	14 (27%)
Adrenal Medulla	(53)	(54)	(53)	(53)	(53)	(51)
Angiectasis			1 (2%)	1 (2%)		
Hyperplasia	18 (34%)	14 (26%)	19 (36%)	14 (26%)	20 (38%)	12 (24%)
Islets, Pancreatic	(53)	(54)	(53)	(53)	(53)	(51)
Hyperplasia	1 (2%)		1 (2%)	1 (2%)		
Parathyroid Gland	(49)	(46)	(50)	(47)	(46)	(48)
Angiectasis				1 (2%)		
Cyst	1 (2%)					
Fibrosis		1 (2%)				
Hyperplasia	2 (4%)			1 (2%)		1 (2%)
Pituitary Gland	(53)	(54)	(53)	(53)	(53)	(50)
Angiectasis	15 (28%)	16 (30%)	20 (38%)	26 (49%)	28 (53%)	14 (28%)
Atypia Cellular				1 (2%)		
Cyst			1 (2%)			1 (2%)
Cytoplasmic Alteration	2 (4%)		1 (2%)		1 (2%)	

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

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
ENDOCRINE SYSTEM - CONT						
Vacuolization Cytoplasmic					1 (2%)	
Pars Distalis, Hyperplasia	23 (43%)	18 (33%)	22 (42%)	16 (30%)	23 (43%)	25 (50%)
Thyroid Gland	(51)	(52)	(53)	(53)	(53)	(51)
Angiectasis		1 (2%)			1 (2%)	
C-Cell, Hyperplasia	19 (37%)	17 (33%)	23 (43%)	17 (32%)	19 (36%)	16 (31%)
Follicular Cell, Hyperplasia	1 (2%)				2 (4%)	2 (4%)
Follicular Cell, Hypertrophy	5 (10%)	9 (17%)	9 (17%)	12 (23%)	10 (19%)	17 (33%)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(53)	(51)	(52)	(53)	(51)	(50)
Atrophy				1 (2%)		
Inflammation	52 (98%)	45 (88%)	41 (79%)	48 (91%)	48 (94%)	46 (92%)
Inflammation, Chronic Active						1 (2%)
Duct, Cyst	49 (92%)	40 (78%)	36 (69%)	43 (81%)	45 (88%)	41 (82%)
Ovary	(53)	(53)	(53)	(53)	(53)	(50)
Atrophy	47 (89%)	43 (81%)	42 (79%)	38 (72%)	44 (83%)	39 (78%)
Cyst	14 (26%)	7 (13%)	17 (32%)	17 (32%)	16 (30%)	17 (34%)
Inflammation, Chronic Active			2 (4%)	1 (2%)	5 (9%)	7 (14%)
Necrosis			1 (2%)			
Interstitial Cell, Hyperplasia	1 (2%)					1 (2%)
Oviduct	(50)	(38)	(44)	(35)	(39)	(45)
Cyst		1 (3%)	2 (5%)	1 (3%)	1 (3%)	
Dilatation			1 (2%)			1 (2%)
Inflammation, Chronic Active	1 (2%)		2 (5%)	1 (3%)	5 (13%)	7 (16%)
Uterus	(53)	(54)	(53)	(53)	(53)	(50)
Adenomyosis	2 (4%)	1 (2%)		1 (2%)		1 (2%)
Angiectasis		1 (2%)			1 (2%)	
Congestion				1 (2%)		
Cyst			1 (2%)	1 (2%)		
Hemorrhage		2 (4%)				
Inflammation, Chronic Active	2 (4%)	1 (2%)	5 (9%)	4 (8%)	2 (4%)	8 (16%)
Inflammation, Suppurative	5 (9%)	6 (11%)	6 (11%)	2 (4%)	16 (30%)	8 (16%)
Metaplasia, Squamous	23 (43%)	29 (54%)	27 (51%)	17 (32%)	27 (51%)	32 (64%)
Thrombosis				1 (2%)	2 (4%)	
Ulcer		1 (2%)				
Cervix, Hyperplasia, Stromal	1 (2%)				2 (4%)	

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

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
GENITAL SYSTEM - CONT						
Cervix, Inflammation, Suppurative	1 (2%)					
Endometrium, Hyperplasia, Cystic	37 (70%)	29 (54%)	32 (60%)	28 (53%)	25 (47%)	21 (42%)
Endometrium, Hyperplasia, Stromal					1 (2%)	
Vagina	(1)	(3)	(2)	(1)	(1)	(3)
Inflammation			1 (50%)			
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(54)	(53)	(53)	(53)	(51)
Hyperplasia	34 (64%)	41 (76%)	40 (75%)	38 (72%)	42 (79%)	46 (90%)
Lymph Node	(3)	(3)	(3)	(2)	(5)	(6)
Hemorrhage			1 (33%)			
Hyperplasia, Lymphoid			1 (33%)			
Hyperplasia, Plasma Cell		1 (33%)	1 (33%)			
Iliac, Ectasia					1 (20%)	
Iliac, Hyperplasia, Plasma Cell					1 (20%)	
Lumbar, Ectasia		1 (33%)	2 (67%)			2 (33%)
Lumbar, Hemorrhage			1 (33%)			1 (17%)
Lumbar, Hyperplasia, Histiocytic					1 (20%)	
Lumbar, Hyperplasia, Plasma Cell					1 (20%)	2 (33%)
Mediastinal, Congestion	3 (100%)					
Mediastinal, Ectasia						2 (33%)
Mediastinal, Hyperplasia, Histiocytic	1 (33%)					
Mediastinal, Hyperplasia, Lymphoid	1 (33%)	1 (33%)				
Mediastinal, Hyperplasia, Plasma Cell	1 (33%)	1 (33%)				
Renal, Ectasia						2 (33%)
Renal, Hyperplasia, Plasma Cell						1 (17%)
Renal, Inflammation, Chronic Active				1 (50%)		
Lymph Node, Mandibular	(51)	(52)	(53)	(51)	(53)	(51)
Congestion					1 (2%)	
Ectasia			1 (2%)		1 (2%)	1 (2%)
Hemorrhage			1 (2%)			
Hyperplasia, Lymphoid	1 (2%)	1 (2%)	2 (4%)	1 (2%)	3 (6%)	1 (2%)
Hyperplasia, Plasma Cell	37 (73%)	36 (69%)	30 (57%)	33 (65%)	37 (70%)	38 (75%)
Inflammation						1 (2%)
Lymph Node, Mesenteric	(52)	(54)	(53)	(53)	(53)	(51)
Ectasia		1 (2%)				
Hemorrhage	1 (2%)					
Hyperplasia, Plasma Cell						1 (2%)
Inflammation, Chronic Active						1 (2%)
Spleen	(53)	(54)	(53)	(53)	(53)	(51)
Hematopoietic Cell Proliferation	46 (87%)	48 (89%)	52 (98%)	48 (91%)	46 (87%)	47 (92%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
HEMATOPOIETIC SYSTEM - CONT						
Hemorrhage						1 (2%)
Infarct						1 (2%)
Necrosis		1 (2%)	1 (2%)			1 (2%)
Pigmentation	47 (89%)	42 (78%)	47 (89%)	49 (92%)	49 (92%)	46 (90%)
Lymphoid Follicle, Atrophy	1 (2%)	6 (11%)	2 (4%)	3 (6%)	3 (6%)	3 (6%)
Red Pulp, Atrophy				2 (4%)		
Thymus	(48)	(53)	(52)	(53)	(53)	(47)
Atrophy	38 (79%)	38 (72%)	37 (71%)	35 (66%)	41 (77%)	30 (64%)
Cyst		1 (2%)				1 (2%)
Hemorrhage		3 (6%)				
INTEGUMENTARY SYSTEM						
Mammary Gland	(53)	(54)	(53)	(53)	(53)	(51)
Cyst	2 (4%)	1 (2%)		2 (4%)	1 (2%)	3 (6%)
Hyperplasia	22 (42%)	23 (43%)	32 (60%)	27 (51%)	32 (60%)	22 (43%)
Inflammation, Chronic Active			1 (2%)			
Inflammation, Granulomatous		2 (4%)	2 (4%)	3 (6%)		1 (2%)
Skin	(53)	(54)	(53)	(53)	(53)	(51)
Cyst						1 (2%)
Cyst Epithelial Inclusion		1 (2%)			1 (2%)	
Inflammation					1 (2%)	
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
Brain	(53)	(54)	(53)	(53)	(53)	(51)
Hemorrhage	1 (2%)		1 (2%)	1 (2%)	2 (4%)	
Hydrocephalus				2 (4%)	1 (2%)	
Hyperplasia, Histiocytic				1 (2%)		
Mineralization				1 (2%)		
Necrosis	1 (2%)			1 (2%)		
Vacuolization Cytoplasmic						1 (2%)
Glial Cell, Hyperplasia		1 (2%)				

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

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
RESPIRATORY SYSTEM						
Lung	(52)	(54)	(53)	(53)	(53)	(51)
Congestion					1 (2%)	
Hemorrhage	1 (2%)					1 (2%)
Infiltration Cellular, Histiocyte	45 (87%)	40 (74%)	40 (75%)	40 (75%)	27 (51%)	28 (55%)
Inflammation	6 (12%)	7 (13%)	2 (4%)	6 (11%)	7 (13%)	9 (18%)
Metaplasia, Squamous				1 (2%)	1 (2%)	1 (2%)
Mineralization				1 (2%)	1 (2%)	
Alveolar Epithelium, Hyperplasia	20 (38%)	21 (39%)	16 (30%)	11 (21%)	9 (17%)	6 (12%)
Mediastinum, Hemorrhage				1 (2%)		
Serosa, Inflammation, Chronic Active				1 (2%)		
Nose	(53)	(54)	(53)	(53)	(53)	(51)
Cyst		1 (2%)				
Inflammation	1 (2%)	6 (11%)	3 (6%)	6 (11%)	6 (11%)	3 (6%)
Goblet Cell, Hyperplasia			2 (4%)	1 (2%)	2 (4%)	
Nasolacrimal Duct, Inflammation	2 (4%)					2 (4%)
Respiratory Epithelium, Hyperplasia			2 (4%)		1 (2%)	
Respiratory Epithelium, Mineralization		1 (2%)				
Septum, Inflammation	4 (8%)	3 (6%)	5 (9%)	3 (6%)	7 (13%)	6 (12%)
Squamous Epithelium, Hyperplasia		1 (2%)				
Turbinate, Inflammation	8 (15%)	3 (6%)	5 (9%)	9 (17%)	10 (19%)	10 (20%)
Trachea	(52)	(54)	(53)	(53)	(53)	(51)
Inflammation						1 (2%)
SPECIAL SENSES SYSTEM						
Eye	(53)	(54)	(53)	(53)	(52)	(51)
Degeneration	1 (2%)					
Anterior Chamber, Exudate					1 (2%)	
Lens, Degeneration				1 (2%)		
Retina, Atrophy	2 (4%)		1 (2%)		1 (2%)	
Harderian Gland	(53)	(54)	(53)	(53)	(53)	(49)
Atrophy		1 (2%)				
Inflammation	20 (38%)	9 (17%)	13 (25%)	16 (30%)	16 (30%)	16 (33%)
URINARY SYSTEM						
Kidney	(53)	(54)	(53)	(53)	(53)	(51)
Accumulation, Hyaline Droplet		3 (6%)	1 (2%)			1 (2%)
Calculus Micro Observation Only	3 (6%)	5 (9%)	4 (8%)	7 (13%)	5 (9%)	1 (2%)
Casts Protein	3 (6%)	2 (4%)	2 (4%)	1 (2%)		1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
URINARY SYSTEM - CONT						
Cyst	1 (2%)			1 (2%)		
Degeneration			1 (2%)			
Hydronephrosis			1 (2%)		1 (2%)	
Infarct	1 (2%)		1 (2%)	2 (4%)		
Inflammation, Chronic Active		2 (4%)			3 (6%)	1 (2%)
Inflammation, Suppurative	1 (2%)	2 (4%)	3 (6%)	2 (4%)	2 (4%)	3 (6%)
Mineralization	40 (75%)	42 (78%)	41 (77%)	39 (74%)	40 (75%)	41 (80%)
Necrosis		1 (2%)				
Nephropathy	34 (64%)	23 (43%)	24 (45%)	33 (62%)	28 (53%)	34 (67%)
Pelvis, Dilatation		2 (4%)				
Pelvis, Inflammation	1 (2%)	4 (7%)	2 (4%)	4 (8%)	5 (9%)	4 (8%)
Renal Tubule, Degeneration			1 (2%)			1 (2%)
Renal Tubule, Hyperplasia		1 (2%)				
Transitional Epithelium, Hyperplasia	1 (2%)	5 (9%)	2 (4%)	4 (8%)	6 (11%)	4 (8%)
Ureter			(1)			
Cyst			1 (100%)			
Urinary Bladder	(53)	(53)	(53)	(53)	(53)	(50)
Calculus Micro Observation Only		1 (2%)				
Inflammation	8 (15%)	11 (21%)	6 (11%)	8 (15%)	13 (25%)	9 (18%)
Transitional Epithelium, Hyperplasia		3 (6%)	2 (4%)	3 (6%)	2 (4%)	3 (6%)

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

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
DISPOSITION SUMMARY	
Animals Initially In Study	50
Early Deaths	
Natural Death	14
Moribund Sacrifice	16
Survivors	
Terminal Sacrifice	20
Animals Examined Microscopically	50
ALIMENTARY SYSTEM	
Esophagus	(49)
Muscularis, Inflammation	3 (6%)
Intestine Large, Rectum	(50)
Parasite Metazoan	3 (6%)
Intestine Large, Cecum	(48)
Inflammation	1 (2%)
Ulcer	1 (2%)
Liver	(50)
Angiectasis	8 (16%)
Basophilic Focus	8 (16%)
Basophilic Focus, Multiple	2 (4%)
Clear Cell Focus	1 (2%)
Degeneration, Cystic	1 (2%)
Eosinophilic Focus	4 (8%)
Eosinophilic Focus, Multiple	10 (20%)
Fatty Change, Diffuse	15 (30%)
Fatty Change, Focal	6 (12%)
Hematopoietic Cell Proliferation	17 (34%)
Hepatodiaphragmatic Nodule	2 (4%)
Hyperplasia, Histiocytic	1 (2%)
Hyperplasia, Nodular	1 (2%)
Inflammation	44 (88%)
Mixed Cell Focus	7 (14%)
Mixed Cell Focus, Multiple	13 (26%)
Necrosis	9 (18%)
Pigmentation	3 (6%)
Bile Duct, Cyst	3 (6%)
Bile Duct, Fibrosis	5 (10%)
Bile Duct, Hyperplasia	12 (24%)
Centrilobular, Degeneration	5 (10%)

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

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
ALIMENTARY SYSTEM - CONT	
Hepatocyte, Hypertrophy	32 (64%)
Oval Cell, Hyperplasia	2 (4%)
Oral Mucosa	(15)
Gingival, Hyperplasia, Squamous	15 (100%)
Pancreas	(50)
Inflammation, Chronic Active	2 (4%)
Acinus, Atrophy	3 (6%)
Acinus, Hyperplasia	2 (4%)
Acinus, Vacuolization Cytoplasmic	1 (2%)
Salivary Glands	(48)
Inflammation, Chronic Active	1 (2%)
Stomach, Forestomach	(50)
Hyperkeratosis	2 (4%)
Hyperplasia, Squamous	5 (10%)
Inflammation	4 (8%)
Mineralization	3 (6%)
Stomach, Glandular	(50)
Inflammation	1 (2%)
Mineralization	3 (6%)
Ulcer	1 (2%)
Serosa, Inflammation	1 (2%)
Tooth	(27)
Peridontal Tissue, Inflammation	27 (100%)
CARDIOVASCULAR SYSTEM	
Heart	(50)
Cardiomyopathy	15 (30%)
Epicardium, Inflammation	1 (2%)
ENDOCRINE SYSTEM	
Adrenal Cortex	(50)
Angiectasis	20 (40%)
Degeneration, Cystic	7 (14%)
Hematopoietic Cell Proliferation	2 (4%)
Hyperplasia	18 (36%)
Hypertrophy	35 (70%)
Necrosis	1 (2%)
Vacuolization Cytoplasmic	12 (24%)
Adrenal Medulla	(50)

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

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
ENDOCRINE SYSTEM - CONT	
Angiectasis	1 (2%)
Hyperplasia	19 (38%)
Parathyroid Gland	(45)
Hyperplasia	1 (2%)
Pituitary Gland	(50)
Angiectasis	24 (48%)
Pars Distalis, Hyperplasia	18 (36%)
Rathke's Cleft, Pars Nervosa, Cyst	1 (2%)
Thyroid Gland	(49)
C-Cell, Hyperplasia	13 (27%)
Follicular Cell, Hypertrophy	12 (24%)
GENERAL BODY SYSTEM	
None	
GENITAL SYSTEM	
Clitoral Gland	(48)
Inflammation	44 (92%)
Duct, Cyst	41 (85%)
Ovary	(49)
Atrophy	41 (84%)
Cyst	16 (33%)
Oviduct	(46)
Dilatation	1 (2%)
Inflammation, Chronic Active	2 (4%)
Uterus	(49)
Cyst	1 (2%)
Inflammation, Chronic Active	1 (2%)
Inflammation, Suppurative	9 (18%)
Metaplasia, Squamous	24 (49%)
Cervix, Cyst	1 (2%)
Cervix, Hyperplasia, Stromal	2 (4%)
Endometrium, Hyperplasia, Cystic	23 (47%)
Vagina	(1)
Inflammation, Chronic Active	1 (100%)
HEMATOPOIETIC SYSTEM	

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

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
HEMATOPOIETIC SYSTEM - CONT	
Bone Marrow	(50)
Hyperplasia	40 (80%)
Lymph Node	(1)
Mediastinal, Hemorrhage	1 (100%)
Lymph Node, Mandibular	(48)
Ectasia	1 (2%)
Hyperplasia, Lymphoid	1 (2%)
Hyperplasia, Plasma Cell	37 (77%)
Inflammation	1 (2%)
Spleen	(50)
Accessory Spleen	1 (2%)
Congestion	1 (2%)
Hematopoietic Cell Proliferation	44 (88%)
Hemorrhage	1 (2%)
Pigmentation	50 (100%)
Lymphoid Follicle, Atrophy	4 (8%)
Thymus	(49)
Atrophy	29 (59%)
Hemorrhage	1 (2%)
Inflammation	1 (2%)
Necrosis, Lymphoid	1 (2%)
INTEGUMENTARY SYSTEM	
Mammary Gland	(50)
Cyst	3 (6%)
Cyst, Multiple	1 (2%)
Hyperplasia	27 (54%)
Inflammation, Granulomatous	2 (4%)
Skin	(50)
Ulcer	1 (2%)
MUSCULOSKELETAL SYSTEM	
None	
NERVOUS SYSTEM	
None	

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

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
RESPIRATORY SYSTEM	
Lung	(50)
Hemorrhage	1 (2%)
Infiltration Cellular, Histiocyte	37 (74%)
Inflammation	9 (18%)
Alveolar Epithelium, Hyperplasia	4 (8%)
Nose	(50)
Inflammation	2 (4%)
Septum, Inflammation	4 (8%)
Turbinate, Inflammation	5 (10%)
SPECIAL SENSES SYSTEM	
Eye	(50)
Retina, Atrophy	2 (4%)
Harderian Gland	(50)
Inflammation	15 (30%)
URINARY SYSTEM	
Kidney	(50)
Casts Protein	4 (8%)
Cyst	1 (2%)
Fibrosis	1 (2%)
Inflammation, Chronic Active	3 (6%)
Inflammation, Suppurative	2 (4%)
Mineralization	38 (76%)
Nephropathy	22 (44%)
Pelvis, Inflammation	3 (6%)
Transitional Epithelium, Hyperplasia	4 (8%)
Urinary Bladder	(49)
Inflammation	10 (20%)
Transitional Epithelium, Hyperplasia	3 (6%)

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

END OF REPORT

FINAL#2

Facility: Battelle Columbus Laboratory

Chemical CAS #: 35065-27-1

Lock Date: 01/16/02

Cage Range: All

Reasons For Removal: 25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

Removal Date Range: All

Treatment Groups: Include All

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

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
DISPOSITION SUMMARY						
Animals Initially in Study	98	86	98	98	98	80
Early Deaths						
Natural Death	11	15	8	9	15	11
Moribund Sacrifice	18	23	17	22	18	19
Dosing Accident				1		
Survivors						
Terminal Sacrifice	24	16	28	20	20	21
Natural Death				1		
Animals Examined Microscopically	53	54	53	53	53	51
ALIMENTARY SYSTEM						
Intestine Large, Colon	(53)	(54)	(53)	(53)	(53)	(50)
Intestine Large, Rectum	(53)	(54)	(53)	(53)	(53)	(50)
Intestine Large, Cecum	(53)	(54)	(53)	(53)	(53)	(50)
Leiomyoma	1 (2%)					
Intestine Small, Duodenum	(53)	(54)	(53)	(53)	(53)	(51)
Intestine Small, Jejunum	(53)	(54)	(53)	(53)	(53)	(50)
Liver	(53)	(54)	(53)	(53)	(53)	(51)
Carcinoma, Metastatic, Uterus					1 (2%)	
Cholangioma					2 (4%)	
Histiocytic Sarcoma				1 (2%)		
Mesentery			(1)		(1)	
Carcinoma, Metastatic, Uterus					1 (100%)	
Oral Mucosa	(21)	(12)	(16)	(12)	(16)	(25)
Gingival, Squamous Cell Carcinoma		2 (17%)		1 (8%)		1 (4%)
Pancreas	(53)	(54)	(53)	(53)	(53)	(51)
Salivary Glands	(51)	(52)	(53)	(52)	(53)	(51)
Stomach, Forestomach	(53)	(54)	(53)	(53)	(53)	(51)
Histiocytic Sarcoma				1 (2%)		
Stomach, Glandular	(53)	(54)	(53)	(53)	(53)	(51)
Histiocytic Sarcoma				1 (2%)		
Tooth	(34)	(13)	(19)	(22)	(23)	(35)
Peridontal Tissue, Neurofibrosarcoma	1 (3%)					

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
CARDIOVASCULAR SYSTEM						
Blood Vessel	(52)	(54)	(53)	(53)	(53)	(51)
Aorta, Fibrosarcoma, Metastatic, Heart	1 (2%)					
Heart	(52)	(54)	(53)	(53)	(53)	(51)
Hemangiosarcoma	1 (2%)					
Histiocytic Sarcoma				1 (2%)		
Schwannoma Malignant		1 (2%)		1 (2%)	1 (2%)	1 (2%)
ENDOCRINE SYSTEM						
Adrenal Cortex	(53)	(54)	(53)	(53)	(53)	(51)
Adenoma				1 (2%)		
Adrenal Medulla	(53)	(54)	(53)	(53)	(53)	(51)
Pheochromocytoma Malignant	1 (2%)	1 (2%)				
Pheochromocytoma Benign	2 (4%)	1 (2%)	4 (8%)	4 (8%)	2 (4%)	2 (4%)
Bilateral, Pheochromocytoma Benign						1 (2%)
Islets, Pancreatic	(53)	(54)	(53)	(53)	(53)	(51)
Adenoma	1 (2%)					
Carcinoma			1 (2%)			
Parathyroid Gland	(49)	(46)	(50)	(47)	(46)	(48)
Adenoma					2 (4%)	
Pituitary Gland	(53)	(54)	(53)	(53)	(53)	(50)
Carcinoma, Metastatic, Oral Mucosa		1 (2%)				
Neurofibrosarcoma, Metastatic, Tooth	1 (2%)					
Pars Distalis, Adenoma	18 (34%)	19 (35%)	19 (36%)	19 (36%)	24 (45%)	11 (22%)
Pars Distalis, Carcinoma						1 (2%)
Thyroid Gland	(51)	(52)	(53)	(53)	(53)	(51)
Bilateral, C-Cell, Adenoma	2 (4%)	4 (8%)			5 (9%)	
C-Cell, Adenoma	14 (27%)	9 (17%)	17 (32%)	11 (21%)	17 (32%)	6 (12%)
C-Cell, Adenoma, Multiple				1 (2%)		1 (2%)
C-Cell, Carcinoma	2 (4%)	2 (4%)	1 (2%)	1 (2%)	2 (4%)	
GENERAL BODY SYSTEM						
None						

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
GENITAL SYSTEM						
Clitoral Gland	(53)	(51)	(52)	(53)	(51)	(50)
Carcinoma		1 (2%)				
Carcinoma, Metastatic, Mammary Gland			1 (2%)			
Ovary	(53)	(53)	(53)	(53)	(53)	(50)
Cystadenoma	1 (2%)					
Granulosa Cell Tumor Malignant				1 (2%)		
Granulosa Cell Tumor Benign			1 (2%)			
Granulosa-Theca Tumor Benign			1 (2%)			
Schwannoma Malignant			1 (2%)			
Uterus	(53)	(54)	(53)	(53)	(53)	(50)
Carcinoma		1 (2%)	1 (2%)		1 (2%)	
Leiomyosarcoma				3 (6%)		
Polyp Stromal	6 (11%)	9 (17%)	4 (8%)	6 (11%)	3 (6%)	2 (4%)
Polyp Stromal, Multiple	1 (2%)					
Schwannoma Malignant		1 (2%)		1 (2%)		
Squamous Cell Carcinoma			2 (4%)			
Cervix, Carcinoma			1 (2%)			
Cervix, Schwannoma Malignant			1 (2%)			
Cervix, Schwannoma Malignant, Metastatic, Vagina						1 (2%)
Cervix, Squamous Cell Carcinoma		1 (2%)				
Vagina	(1)	(3)	(2)	(1)	(1)	(3)
Fibrosarcoma		2 (67%)				
Fibrous Histiocytoma, Metastatic, Skin					1 (100%)	
Sarcoma		1 (33%)				
Schwannoma Malignant	1 (100%)					3 (100%)
Squamous Cell Carcinoma			1 (50%)	1 (100%)		
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(54)	(53)	(53)	(53)	(51)
Histiocytic Sarcoma				1 (2%)		
Lipoma	1 (2%)					
Lymph Node	(3)	(3)	(3)	(2)	(5)	(6)
Deep Cervical, Carcinoma, Metastatic, Thyroid Gland					1 (20%)	
Mediastinal, Carcinoma, Metastatic, Uterus					1 (20%)	
Mediastinal, Histiocytic Sarcoma				1 (50%)		
Lymph Node, Mandibular	(51)	(52)	(53)	(51)	(53)	(51)
Lymph Node, Mesenteric	(52)	(54)	(53)	(53)	(53)	(51)
Carcinoma, Metastatic, Uterus					1 (2%)	

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
HEMATOPOIETIC SYSTEM - cont						
Histiocytic Sarcoma				1 (2%)		
Spleen	(53)	(54)	(53)	(53)	(53)	(51)
Histiocytic Sarcoma				1 (2%)		
Thymus	(48)	(53)	(52)	(53)	(53)	(47)
Fibrosarcoma, Metastatic, Heart	1 (2%)					
Histiocytic Sarcoma				1 (2%)		
INTEGUMENTARY SYSTEM						
Mammary Gland	(53)	(54)	(53)	(53)	(53)	(51)
Adenoma	1 (2%)		1 (2%)	1 (2%)	3 (6%)	2 (4%)
Adenoma, Multiple	1 (2%)					
Carcinoma	8 (15%)	6 (11%)	7 (13%)	4 (8%)	6 (11%)	2 (4%)
Carcinoma, Multiple				1 (2%)		
Fibroadenoma	22 (42%)	21 (39%)	22 (42%)	22 (42%)	27 (51%)	24 (47%)
Fibroadenoma, Multiple	19 (36%)	13 (24%)	14 (26%)	13 (25%)	12 (23%)	8 (16%)
Skin	(53)	(54)	(53)	(53)	(53)	(51)
Basal Cell Adenoma					1 (2%)	
Basal Cell Carcinoma		1 (2%)				1 (2%)
Fibroma			2 (4%)	1 (2%)	1 (2%)	
Fibrosarcoma		1 (2%)			1 (2%)	
Fibrous Histiocytoma			1 (2%)		1 (2%)	
Histiocytic Sarcoma				1 (2%)		
Keratoacanthoma		1 (2%)		1 (2%)		
Lipoma			1 (2%)			
Sarcoma		1 (2%)				
Schwannoma Malignant						1 (2%)
Schwannoma Malignant, Metastatic, Vagina	1 (2%)					
Squamous Cell Papilloma					1 (2%)	
Subcutaneous Tissue, Sarcoma			1 (2%)			
MUSCULOSKELETAL SYSTEM						
None						

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
NERVOUS SYSTEM						
Brain	(53)	(54)	(53)	(53)	(53)	(51)
Astrocytoma Malignant				1 (2%)		
Carcinoma, Metastatic, Pituitary Gland						1 (2%)
Carcinoma, Metastatic, Oral Mucosa		1 (2%)				
Neurofibrosarcoma, Metastatic, Tooth	1 (2%)					
RESPIRATORY SYSTEM						
Lung	(52)	(54)	(53)	(53)	(53)	(51)
Alveolar/Bronchiolar Adenoma	1 (2%)				2 (4%)	
Basal Cell Carcinoma, Metastatic, Skin						1 (2%)
Carcinoma, Metastatic, Mammary Gland		1 (2%)			1 (2%)	1 (2%)
Carcinoma, Metastatic, Uterus					1 (2%)	
Carcinoma, Metastatic, Oral Mucosa		1 (2%)				
Fibrous Histiocytoma, Metastatic, Skin			1 (2%)			
Histiocytic Sarcoma				1 (2%)		
Mediastinum, Fibrosarcoma, Metastatic, Heart	1 (2%)					
Nose	(53)	(54)	(53)	(53)	(53)	(51)
Trachea	(52)	(54)	(53)	(53)	(53)	(51)
SPECIAL SENSES SYSTEM						
Eye	(53)	(54)	(53)	(53)	(52)	(51)
Neurofibrosarcoma, Metastatic, Tooth	1 (2%)					
Harderian Gland	(53)	(54)	(53)	(53)	(53)	(49)
Carcinoma, Metastatic, Oral Mucosa		1 (2%)				
Neurofibrosarcoma, Metastatic, Tooth	1 (2%)					
URINARY SYSTEM						
Kidney	(53)	(54)	(53)	(53)	(53)	(51)
Carcinoma, Metastatic, Mammary Gland						1 (2%)
Histiocytic Sarcoma				1 (2%)		
Nephroblastoma				1 (2%)		
Stromal Nephroma		1 (2%)				1 (2%)
Bilateral, Renal Tubule, Carcinoma						1 (2%)
Renal Tubule, Adenoma			1 (2%)			
Urinary Bladder	(53)	(53)	(53)	(53)	(53)	(50)

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
SYSTEMIC LESIONS						
Multiple Organs	*(53)	*(54)	*(53)	*(53)	*(53)	*(51)
Histiocytic Sarcoma				1 (2%)		
Leukemia Mononuclear	1 (2%)					
Lymphoma Malignant	2 (4%)				3 (6%)	

* Number of animals with any tissue examined microscopically

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
TUMOR SUMMARY						
Total Animals with Primary Neoplasms (b)	52	51	49	48	51	48
Total Primary Neoplasms	108	100	105	97	117	69
Total Animals with Benign Neoplasms	50	41	45	46	49	40
Total Benign Neoplasms	91	77	87	80	102	57
Total Animals with Malignant Neoplasms	12	20	16	14	14	11
Total Malignant Neoplasms	17	23	18	17	15	12
Total Animals with Metastatic Neoplasms	3	2	2		4	4
Total Metastatic Neoplasm	8	5	2		8	5
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

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
DISPOSITION SUMMARY	
Animals Initially in Study	50
Early Deaths	
Natural Death	14
Moribund Sacrifice	16
Survivors	
Terminal Sacrifice	20
Animals Examined Microscopically	50
ALIMENTARY SYSTEM	
Intestine Small, Jejunum	(49)
Fibrosarcoma	1 (2%)
Liver	(50)
Cholangioma	1 (2%)
Cholangioma, Multiple	1 (2%)
Pancreas	(50)
Acinus, Adenoma	1 (2%)
CARDIOVASCULAR SYSTEM	
Heart	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)
ENDOCRINE SYSTEM	
Adrenal Medulla	(50)
Pheochromocytoma Benign	6 (12%)
Islets, Pancreatic	(50)
Adenoma	1 (2%)
Carcinoma	1 (2%)
Parathyroid Gland	(45)
Adenoma	1 (2%)
Pituitary Gland	(50)
Pars Distalis, Adenoma	23 (46%)
Pars Distalis, Carcinoma	1 (2%)
Thyroid Gland	(49)
C-Cell, Adenoma	18 (37%)

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
ENDOCRINE SYSTEM - cont	
C-Cell, Carcinoma	3 (6%)
Follicular Cell, Adenoma	2 (4%)
GENERAL BODY SYSTEM	
None	
GENITAL SYSTEM	
Ovary	(49)
Cystadenoma	1 (2%)
Granulosa-Theca Tumor Benign	1 (2%)
Uterus	(49)
Carcinoma	1 (2%)
Polyp Stromal	4 (8%)
Cervix, Schwannoma Malignant	1 (2%)
HEMATOPOIETIC SYSTEM	
None	
INTEGUMENTARY SYSTEM	
Mammary Gland	(50)
Carcinoma	10 (20%)
Fibroadenoma	16 (32%)
Fibroadenoma, Multiple	14 (28%)
Skin	(50)
Basal Cell Carcinoma	1 (2%)
Fibroma	2 (4%)
Fibrosarcoma	4 (8%)
Fibrous Histiocytoma	1 (2%)
Schwannoma Malignant	1 (2%)

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
MUSCULOSKELETAL SYSTEM	
Bone	(50)
Schwannoma Malignant, Metastatic, Skin	1 (2%)
NERVOUS SYSTEM	
Brain	(50)
Carcinoma, Metastatic, Pituitary Gland	1 (2%)
Meninges, Sarcoma	1 (2%)
Meninges, Schwannoma Malignant, Metastatic, Skin	1 (2%)
RESPIRATORY SYSTEM	
Lung	(50)
Carcinoma, Metastatic, Mammary Gland	1 (2%)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)
Nose	(50)
Basal Cell Carcinoma, Metastatic, Skin	1 (2%)
SPECIAL SENSES SYSTEM	
Eye	(50)
Optic Nerve, Schwannoma Malignant, Metastatic, Skin	1 (2%)
Harderian Gland	(50)
Schwannoma Malignant, Metastatic, Skin	1 (2%)
URINARY SYSTEM	
Kidney	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)
Stromal Nephroma	1 (2%)

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
TUMOR SUMMARY	
Total Animals with Primary Neoplasms (b)	49
Total Primary Neoplasms	119
Total Animals with Benign Neoplasms	44
Total Benign Neoplasms	92
Total Animals with Malignant Neoplasms	23
Total Malignant Neoplasms	27
Total Animals with Metastatic Neoplasms	5
Total Metastatic Neoplasm	10
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#2 CONTROL VS. TREATED

REASONS FOR REMOVAL:
25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:

INCLUDE 001	0	UG/KG
INCLUDE 002	10	UG/KG
INCLUDE 003	100	UG/KG
INCLUDE 004	300	UG/KG
INCLUDE 005	1000	UG/KG
INCLUDE 006	3000	UG/KG

NTP
LAB: Battelle Columbus
EXPERIMENT: 96021 TEST: 01
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD
Rats(SPRAGUE-DAWLEY)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB 153)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 09:21:09

NTP C#: C96021
CAS: 35065-27-1

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
Brain
Clitoral/Preputial Gland
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Ovary
Parathyroid Gland
Pituitary Gland
Thyroid Gland

NTP
LAB: Battelle Columbus
EXPERIMENT: 96021 TEST: 01
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB 153)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 09:21:09

NTP C#: C96021
CAS: 35065-27-1

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TOXIC EQUIVALENCY FACTOR EVALUATION (

Female Rats

Organ	Morphology
Thyroid Gland: C-Cell	Adenoma
	Carcinoma or Adenoma
Uterus	Polyp Stromal
Vagina	Schwannoma Malignant
All Organs	Benign Tumors
	Malignant Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Adrenal Medulla						
Pheochromocytoma Benign						
TUMOR RATES						
OVERALL (a)	2/53 (4%)	1/54 (2%)	4/53 (8%)	4/53 (8%)	2/53 (4%)	3/51 (6%)
POLY-3 RATE (b)	2/39.13	1/31.01	4/41.12	4/36.33	2/38.33	3/33.81
POLY-3 PERCENT (g)	5.1%	3.2%	9.7%	11.0%	5.2%	8.9%
TERMINAL (d)	1/24 (4%)	1/16 (6%)	4/28 (14%)	4/21 (19%)	2/20 (10%)	1/21 (5%)
FIRST INCIDENCE	701	731 (T)	731 (T)	731 (T)	731 (T)	586
STATISTICAL TESTS						
LIFE TABLE	P=0.467	P=0.635N	P=0.412	P=0.276	P=0.641	P=0.421
POLY 3	P=0.486	P=0.580N	P=0.359	P=0.301	P=0.688	P=0.433
POLY 1.5	P=0.490	P=0.551N	P=0.351	P=0.309	P=0.691	P=0.449
POLY 6	P=0.486	P=0.607N	P=0.374	P=0.296	P=0.682	P=0.426
LOGISTIC REGRESSION	P=0.447	P=0.629N	P=0.409	P=0.287	P=0.676	P=0.425
COCH-ARM / FISHERS	P=0.489	P=0.493N	P=0.339	P=0.339	P=0.691N	P=0.482
ORDER RESTRICTED	P=0.414	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Adrenal Medulla						
Pheochromocytoma: Benign, Complex, Malignant, NOS						
TUMOR RATES						
OVERALL (a)	3/53 (6%)	2/54 (4%)	4/53 (8%)	4/53 (8%)	2/53 (4%)	3/51 (6%)
POLY-3 RATE (b)	3/39.55	2/31.01	4/41.12	4/36.33	2/38.33	3/33.81
POLY-3 PERCENT (g)	7.6%	6.5%	9.7%	11.0%	5.2%	8.9%
TERMINAL (d)	1/24 (4%)	2/16 (13%)	4/28 (14%)	4/21 (19%)	2/20 (10%)	1/21 (5%)
FIRST INCIDENCE	608	731 (T)	731 (T)	731 (T)	731 (T)	586
STATISTICAL TESTS						
LIFE TABLE	P=0.589N	P=0.664N	P=0.573	P=0.434	P=0.553N	P=0.569
POLY 3	P=0.572N	P=0.609N	P=0.521	P=0.453	P=0.514N	P=0.589
POLY 1.5	P=0.565N	P=0.569N	P=0.514	P=0.464	P=0.506N	P=0.608
POLY 6	P=0.578N	P=0.647N	P=0.534	P=0.443	P=0.527N	P=0.578
LOGISTIC REGRESSION	P=0.579	P=0.638N	P=0.551	P=0.457	P=0.514N	P=0.597
COCH-ARM / FISHERS	P=0.563N	P=0.491N	P=0.500	P=0.500	P=0.500N	P=0.642
ORDER RESTRICTED	P=0.686N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Liver						
Cholangioma						
TUMOR RATES						
OVERALL (a)	0/53 (0%)	0/54 (0%)	0/53 (0%)	0/53 (0%)	2/53 (4%)	0/51 (0%)
POLY-3 RATE (b)	0/39.01	0/31.01	0/41.12	0/36.33	2/38.45	0/33.11
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	5.2%	0.0%
TERMINAL (d)	0/24 (0%)	0/16 (0%)	0/28 (0%)	0/21 (0%)	1/20 (5%)	0/21 (0%)
FIRST INCIDENCE	---	---	---	---	702	---
STATISTICAL TESTS						
LIFE TABLE	P=0.616	(e)	(e)	(e)	P=0.224	(e)
POLY 3	P=0.568	(e)	(e)	(e)	P=0.233	(e)
POLY 1.5	P=0.587	(e)	(e)	(e)	P=0.236	(e)
POLY 6	P=0.552	(e)	(e)	(e)	P=0.230	(e)
LOGISTIC REGRESSION	P=0.605	(e)	(e)	(e)	P=0.226	(e)
COCH-ARM / FISHERS	P=0.615	(e)	(e)	(e)	P=0.248	(e)
ORDER RESTRICTED	P=0.187	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Lung						
Alveolar/Bronchiolar Adenoma						
TUMOR RATES						
OVERALL (a)	1/52 (2%)	0/54 (0%)	0/53 (0%)	0/53 (0%)	2/53 (4%)	0/51 (0%)
POLY-3 RATE (b)	1/38.91	0/31.01	0/41.12	0/36.33	2/38.33	0/33.11
POLY-3 PERCENT (g)	2.6%	0.0%	0.0%	0.0%	5.2%	0.0%
TERMINAL (d)	0/24 (0%)	0/16 (0%)	0/28 (0%)	0/21 (0%)	2/20 (10%)	0/21 (0%)
FIRST INCIDENCE	701	---	---	---	731 (T)	---
STATISTICAL TESTS						
LIFE TABLE	P=0.687N	P=0.573N	P=0.465N	P=0.524N	P=0.453	P=0.533N
POLY 3	P=0.693N	P=0.545N	P=0.489N	P=0.514N	P=0.495	P=0.532N
POLY 1.5	P=0.685N	P=0.527N	P=0.492N	P=0.510N	P=0.501	P=0.522N
POLY 6	P=0.700	P=0.561N	P=0.483N	P=0.516N	P=0.487	P=0.540N
LOGISTIC REGRESSION	P=0.697N	P=0.561N	P=0.485N	P=0.514N	P=0.481	P=0.536N
COCH-ARM / FISHERS	P=0.677N	P=0.491N	P=0.495N	P=0.495N	P=0.507	P=0.505N
ORDER RESTRICTED	P=0.319N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Mammary Gland Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	2/53 (4%)	0/54 (0%)	1/53 (2%)	1/53 (2%)	3/53 (6%)	2/51 (4%)
POLY-3 RATE (b)	2/39.01	0/31.01	1/41.12	1/36.33	3/38.33	2/33.52
POLY-3 PERCENT (g)	5.1%	0.0%	2.4%	2.8%	7.8%	6.0%
TERMINAL (d)	2/24 (8%)	0/16 (0%)	1/28 (4%)	1/21 (5%)	3/20 (15%)	1/21 (5%)
FIRST INCIDENCE	731 (T)	---	731 (T)	731 (T)	731 (T)	612
STATISTICAL TESTS						
LIFE TABLE	P=0.253	P=0.330N	P=0.446N	P=0.547N	P=0.415	P=0.636
POLY 3	P=0.255	P=0.291N	P=0.482N	P=0.525N	P=0.492	P=0.639
POLY 1.5	P=0.262	P=0.271N	P=0.489N	P=0.520N	P=0.497	P=0.653
POLY 6	P=0.250	P=0.310N	P=0.469N	P=0.527N	P=0.485	P=0.633
LOGISTIC REGRESSION	P=0.236	(e)	P=0.446N	P=0.547N	P=0.415	P=0.628
COCH-ARM / FISHERS	P=0.268	P=0.243N	P=0.500N	P=0.500N	P=0.500	P=0.676
ORDER RESTRICTED	P=0.330	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Mammary Gland Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	8/53 (15%)	6/54 (11%)	7/53 (13%)	5/53 (9%)	6/53 (11%)	2/51 (4%)
POLY-3 RATE (b)	8/39.57	6/34.92	7/44.00	5/38.04	6/39.84	2/34.52
POLY-3 PERCENT (g)	20.2%	17.2%	15.9%	13.1%	15.1%	5.8%
TERMINAL (d)	6/24 (25%)	1/16 (6%)	2/28 (7%)	1/21 (5%)	4/20 (20%)	0/21 (0%)
FIRST INCIDENCE	608	250	443	263	452	79
STATISTICAL TESTS						
LIFE TABLE	P=0.072N	P=0.602	P=0.416N	P=0.353N	P=0.486N	P=0.083N
POLY 3	P=0.072N	P=0.485N	P=0.410N	P=0.297N	P=0.378N	P=0.068N
POLY 1.5	P=0.063N	P=0.448N	P=0.446N	P=0.298N	P=0.379N	P=0.061N
POLY 6	P=0.082N	P=0.514N	P=0.363N	P=0.290N	P=0.384N	P=0.071N
LOGISTIC REGRESSION	P=0.054N	P=0.368N	P=0.493N	P=0.310N	P=0.398N	P=0.060N
COCH-ARM / FISHERS	P=0.058N	P=0.373N	P=0.500N	P=0.278N	P=0.388N	P=0.053N
ORDER RESTRICTED	P=0.066N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Mammary Gland Carcinoma or Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	9/53 (17%)	6/54 (11%)	8/53 (15%)	5/53 (9%)	7/53 (13%)	3/51 (6%)
POLY-3 RATE (b)	9/39.57	6/34.92	8/44.00	5/38.04	7/39.84	3/34.52
POLY-3 PERCENT (g)	22.8%	17.2%	18.2%	13.1%	17.6%	8.7%
TERMINAL (d)	7/24 (29%)	1/16 (6%)	3/28 (11%)	1/21 (5%)	5/20 (25%)	1/21 (5%)
FIRST INCIDENCE	608	250	443	263	452	79
STATISTICAL TESTS						
LIFE TABLE	P=0.116N	P=0.531N	P=0.404N	P=0.265N	P=0.506N	P=0.106N
POLY 3	P=0.118N	P=0.378N	P=0.403N	P=0.208N	P=0.383N	P=0.090N
POLY 1.5	P=0.105N	P=0.344N	P=0.442N	P=0.210N	P=0.384N	P=0.081N
POLY 6	P=0.134N	P=0.405N	P=0.351N	P=0.201N	P=0.389N	P=0.095N
LOGISTIC REGRESSION	P=0.094N	P=0.290N	P=0.483N	P=0.225N	P=0.408N	P=0.087N
COCH-ARM / FISHERS	P=0.097N	P=0.276N	P=0.500N	P=0.195N	P=0.393N	P=0.070N
ORDER RESTRICTED	P=0.086N	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Mammary Gland Fibroadenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	41/53 (77%)	34/54 (63%)	36/53 (68%)	35/53 (66%)	39/53 (74%)	32/51 (63%)
POLY-3 RATE (b)	41/49.26	34/43.20	36/47.95	35/46.05	39/49.19	32/44.62
POLY-3 PERCENT (g)	83.2%	78.7%	75.1%	76.0%	79.3%	71.7%
TERMINAL (d)	19/24 (79%)	13/16 (81%)	22/28 (79%)	14/21 (67%)	13/20 (65%)	13/21 (62%)
FIRST INCIDENCE	399	310	418	269	341	360
STATISTICAL TESTS						
LIFE TABLE	P=0.459N	P=0.291	P=0.103N	P=0.422N	P=0.481	P=0.393N
POLY 3	P=0.190N	P=0.377N	P=0.214N	P=0.255N	P=0.399N	P=0.123N
POLY 1.5	P=0.208N	P=0.237N	P=0.188N	P=0.230N	P=0.393N	P=0.103N
POLY 6	P=0.182N	P=0.513N	P=0.262N	P=0.266N	P=0.398N	P=0.148N
LOGISTIC REGRESSION	P=0.295N	P=0.206N	P=0.166N	P=0.192N	P=0.413N	P=0.095N
COCH-ARM / FISHERS	P=0.266N	P=0.078N	P=0.192N	P=0.140N	P=0.411N	P=0.078N
ORDER RESTRICTED	P=0.128N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

	Females					
Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Mammary Gland Fibroma, Fibroadenoma or Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	41/53 (77%)	34/54 (63%)	36/53 (68%)	36/53 (68%)	41/53 (77%)	33/51 (65%)
POLY-3 RATE (b)	41/49.26	34/43.20	36/47.95	36/46.05	41/49.19	33/44.62
POLY-3 PERCENT (g)	83.2%	78.7%	75.1%	78.2%	83.4%	74.0%
TERMINAL (d)	19/24 (79%)	13/16 (81%)	22/28 (79%)	15/21 (71%)	15/20 (75%)	14/21 (67%)
FIRST INCIDENCE	399	310	418	269	341	360
STATISTICAL TESTS						
LIFE TABLE	P=0.527	P=0.291	P=0.103N	P=0.480N	P=0.366	P=0.452N
POLY 3	P=0.294N	P=0.377N	P=0.214N	P=0.349N	P=0.607	P=0.184N
POLY 1.5	P=0.310N	P=0.237N	P=0.188N	P=0.313N	P=0.599N	P=0.154N
POLY 6	P=0.291N	P=0.513N	P=0.262N	P=0.368N	P=0.609	P=0.222N
LOGISTIC REGRESSION	P=0.401N	P=0.206N	P=0.166N	P=0.262N	P=0.590	P=0.141N
COCH-ARM / FISHERS	P=0.363N	P=0.078N	P=0.192N	P=0.192N	P=0.592N	P=0.114N
ORDER RESTRICTED	P=0.206N	(e)	(e)	(e)	(e)	(e)

	Females					
Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	43/53 (81%)	37/54 (69%)	40/53 (75%)	38/53 (72%)	42/53 (79%)	34/51 (67%)
POLY-3 RATE (b)	43/49.39	37/45.93	40/50.65	38/47.11	42/49.93	34/45.62
POLY-3 PERCENT (g)	87.1%	80.6%	79.0%	80.7%	84.1%	74.5%
TERMINAL (d)	20/24 (83%)	13/16 (81%)	22/28 (79%)	15/21 (71%)	15/20 (75%)	14/21 (67%)
FIRST INCIDENCE	399	250	418	263	341	79
STATISTICAL TESTS						
LIFE TABLE	P=0.408N	P=0.230	P=0.173N	P=0.492N	P=0.414	P=0.409N
POLY 3	P=0.158N	P=0.260N	P=0.195N	P=0.268N	P=0.445N	P=0.081N
POLY 1.5	P=0.147N	P=0.184N	P=0.223N	P=0.252N	P=0.453N	P=0.069N
POLY 6	P=0.176N	P=0.357N	P=0.185N	P=0.277N	P=0.437N	P=0.103N
LOGISTIC REGRESSION	P=0.199N	P=0.186N	P=0.308N	P=0.247N	P=0.502N	P=0.080N
COCH-ARM / FISHERS	P=0.187N	P=0.100N	P=0.319N	P=0.180N	P=0.500N	P=0.072N
ORDER RESTRICTED	P=0.077N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	2/54 (4%)	0/53 (0%)	1/53 (2%)	0/53 (0%)	1/51 (2%)
POLY-3 RATE (b)	0/39.01	2/31.41	0/41.12	1/36.33	0/38.33	1/33.11
POLY-3 PERCENT (g)	0.0%	6.4%	0.0%	2.8%	0.0%	3.0%
TERMINAL (d)	0/24 (0%)	1/16 (6%)	0/28 (0%)	1/21 (5%)	0/20 (0%)	1/21 (5%)
FIRST INCIDENCE	---	616	---	731 (T)	---	731 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.591	P=0.177	(e)	P=0.473	(e)	P=0.473
POLY 3	P=0.545	P=0.192	(e)	P=0.486	(e)	P=0.467
POLY 1.5	P=0.566	P=0.207	(e)	P=0.488	(e)	P=0.476
POLY 6	P=0.524	P=0.180	(e)	P=0.485	(e)	P=0.461
LOGISTIC REGRESSION	P=0.588	P=0.188	(e)	P=0.473	(e)	P=0.473
COCH-ARM / FISHERS	P=0.604	P=0.252	(e)	P=0.500	(e)	P=0.490
ORDER RESTRICTED	P=0.309	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	2/54 (4%)	0/53 (0%)	1/53 (2%)	0/53 (0%)	1/51 (2%)
POLY-3 RATE (b)	0/39.01	2/31.41	0/41.12	1/36.33	0/38.33	1/33.11
POLY-3 PERCENT (g)	0.0%	6.4%	0.0%	2.8%	0.0%	3.0%
TERMINAL (d)	0/24 (0%)	1/16 (6%)	0/28 (0%)	1/21 (5%)	0/20 (0%)	1/21 (5%)
FIRST INCIDENCE	---	616	---	731 (T)	---	731 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.591	P=0.177	(e)	P=0.473	(e)	P=0.473
POLY 3	P=0.545	P=0.192	(e)	P=0.486	(e)	P=0.467
POLY 1.5	P=0.566	P=0.207	(e)	P=0.488	(e)	P=0.476
POLY 6	P=0.524	P=0.180	(e)	P=0.485	(e)	P=0.461
LOGISTIC REGRESSION	P=0.588	P=0.188	(e)	P=0.473	(e)	P=0.473
COCH-ARM / FISHERS	P=0.604	P=0.252	(e)	P=0.500	(e)	P=0.490
ORDER RESTRICTED	P=0.309	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Oral Mucosa Squamous Cell Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	2/54 (4%)	0/53 (0%)	1/53 (2%)	0/53 (0%)	1/51 (2%)
POLY-3 RATE (b)	0/39.01	2/31.41	0/41.12	1/36.33	0/38.33	1/33.11
POLY-3 PERCENT (g)	0.0%	6.4%	0.0%	2.8%	0.0%	3.0%
TERMINAL (d)	0/24 (0%)	1/16 (6%)	0/28 (0%)	1/21 (5%)	0/20 (0%)	1/21 (5%)
FIRST INCIDENCE	---	616	---	731 (T)	---	731 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.591	P=0.177	(e)	P=0.473	(e)	P=0.473
POLY 3	P=0.545	P=0.192	(e)	P=0.486	(e)	P=0.467
POLY 1.5	P=0.566	P=0.207	(e)	P=0.488	(e)	P=0.476
POLY 6	P=0.524	P=0.180	(e)	P=0.485	(e)	P=0.461
LOGISTIC REGRESSION	P=0.588	P=0.188	(e)	P=0.473	(e)	P=0.473
COCH-ARM / FISHERS	P=0.604	P=0.252	(e)	P=0.500	(e)	P=0.490
ORDER RESTRICTED	P=0.309	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Parathyroid Gland Adenoma						
TUMOR RATES						
OVERALL (a)	0/49 (0%)	0/46 (0%)	0/50 (0%)	0/47 (0%)	2/46 (4%)	0/48 (0%)
POLY-3 RATE (b)	0/36.68	0/27.75	0/38.12	0/32.21	2/33.00	0/30.97
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	6.1%	0.0%
TERMINAL (d)	0/23 (0%)	0/15 (0%)	0/25 (0%)	0/18 (0%)	1/16 (6%)	0/20 (0%)
FIRST INCIDENCE	---	---	---	---	579	---
STATISTICAL TESTS						
LIFE TABLE	P=0.609	(e)	(e)	(e)	P=0.200	(e)
POLY 3	P=0.565	(e)	(e)	(e)	P=0.213	(e)
POLY 1.5	P=0.586	(e)	(e)	(e)	P=0.218	(e)
POLY 6	P=0.551	(e)	(e)	(e)	P=0.206	(e)
LOGISTIC REGRESSION	P=0.614	(e)	(e)	(e)	P=0.220	(e)
COCH-ARM / FISHERS	P=0.621	(e)	(e)	(e)	P=0.232	(e)
ORDER RESTRICTED	P=0.165	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma						
TUMOR RATES						
OVERALL (a)	18/53 (34%)	19/54 (35%)	19/53 (36%)	19/53 (36%)	24/53 (45%)	11/50 (22%)
POLY-3 RATE (b)	18/41.75	19/34.40	19/42.89	19/39.93	24/41.43	11/34.40
POLY-3 PERCENT (g)	43.1%	55.2%	44.3%	47.6%	57.9%	32.0%
TERMINAL (d)	10/24 (42%)	10/16 (63%)	13/28 (46%)	9/21 (43%)	12/20 (60%)	7/21 (33%)
FIRST INCIDENCE	211	502	429	443	579	486
STATISTICAL TESTS						
LIFE TABLE	P=0.114N	P=0.101	P=0.440N	P=0.376	P=0.099	P=0.217N
POLY 3	P=0.120N	P=0.195	P=0.545	P=0.425	P=0.116	P=0.218N
POLY 1.5	P=0.096N	P=0.287	P=0.524	P=0.422	P=0.129	P=0.184N
POLY 6	P=0.159N	P=0.142	P=0.579	P=0.450	P=0.109	P=0.255N
LOGISTIC REGRESSION	P=0.095N	P=0.175	P=0.574	P=0.406	P=0.128	P=0.204N
COCH-ARM / FISHERS	P=0.081N	P=0.528	P=0.500	P=0.500	P=0.160	P=0.129N
ORDER RESTRICTED	P=0.095N	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma						
TUMOR RATES						
OVERALL (a)	18/53 (34%)	19/54 (35%)	19/53 (36%)	19/53 (36%)	24/53 (45%)	12/50 (24%)
POLY-3 RATE (b)	18/41.75	19/34.40	19/42.89	19/39.93	24/41.43	12/34.62
POLY-3 PERCENT (g)	43.1%	55.2%	44.3%	47.6%	57.9%	34.7%
TERMINAL (d)	10/24 (42%)	10/16 (63%)	13/28 (46%)	9/21 (43%)	12/20 (60%)	7/21 (33%)
FIRST INCIDENCE	211	502	429	443	579	486
STATISTICAL TESTS						
LIFE TABLE	P=0.171N	P=0.101	P=0.440N	P=0.376	P=0.099	P=0.294N
POLY 3	P=0.182N	P=0.195	P=0.545	P=0.425	P=0.116	P=0.298N
POLY 1.5	P=0.151N	P=0.287	P=0.524	P=0.422	P=0.129	P=0.257N
POLY 6	P=0.226N	P=0.142	P=0.579	P=0.450	P=0.109	P=0.336N
LOGISTIC REGRESSION	P=0.152N	P=0.175	P=0.574	P=0.406	P=0.128	P=0.283N
COCH-ARM / FISHERS	P=0.127N	P=0.528	P=0.500	P=0.500	P=0.160	P=0.185N
ORDER RESTRICTED	P=0.158N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

			Females			
Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
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)	0/53 (0%)	2/54 (4%)	0/53 (0%)	1/53 (2%)	2/53 (4%)	1/51 (2%)
POLY-3 RATE (b)	0/39.01	2/31.14	0/41.12	1/36.33	2/39.53	1/33.89
POLY-3 PERCENT (g)	0.0%	6.4%	0.0%	2.8%	5.1%	3.0%
TERMINAL (d)	0/24 (0%)	1/16 (6%)	0/28 (0%)	1/21 (5%)	0/20 (0%)	0/21 (0%)
FIRST INCIDENCE	---	696	---	731 (T)	479	443
STATISTICAL TESTS						
LIFE TABLE	P=0.479	P=0.158	(e)	P=0.473	P=0.239	P=0.482
POLY 3	P=0.436	P=0.190	(e)	P=0.486	P=0.239	P=0.472
POLY 1.5	P=0.459	P=0.207	(e)	P=0.488	P=0.239	P=0.479
POLY 6	P=0.415	P=0.177	(e)	P=0.485	P=0.240	P=0.468
LOGISTIC REGRESSION	P=0.500	P=0.164	(e)	P=0.473	P=0.224	P=0.576
COCH-ARM / FISHERS	P=0.499	P=0.252	(e)	P=0.500	P=0.248	P=0.490
ORDER RESTRICTED	P=0.255	(e)	(e)	(e)	(e)	(e)

			Females			
Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Skin Fibroma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	0/54 (0%)	2/53 (4%)	1/53 (2%)	1/53 (2%)	0/51 (0%)
POLY-3 RATE (b)	0/39.01	0/31.01	2/41.59	1/36.49	1/38.33	0/33.11
POLY-3 PERCENT (g)	0.0%	0.0%	4.8%	2.7%	2.6%	0.0%
TERMINAL (d)	0/24 (0%)	0/16 (0%)	1/28 (4%)	0/21 (0%)	1/20 (5%)	0/21 (0%)
FIRST INCIDENCE	---	---	591	691	731 (T)	---
STATISTICAL TESTS						
LIFE TABLE	P=0.449N	(e)	P=0.257	P=0.485	P=0.464	(e)
POLY 3	P=0.420N	(e)	P=0.251	P=0.487	P=0.497	(e)
POLY 1.5	P=0.421N	(e)	P=0.246	P=0.489	P=0.499	(e)
POLY 6	P=0.418N	(e)	P=0.261	P=0.487	P=0.494	(e)
LOGISTIC REGRESSION	P=0.443N	(e)	P=0.240	P=0.486	P=0.464	(e)
COCH-ARM / FISHERS	P=0.429N	(e)	P=0.248	P=0.500	P=0.500	(e)
ORDER RESTRICTED	P=0.365	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Skin Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	2/54 (4%)	3/53 (6%)	1/53 (2%)	3/53 (6%)	0/51 (0%)
POLY-3 RATE (b)	0/39.01	2/32.88	3/41.86	1/36.49	3/39.06	0/33.11
POLY-3 PERCENT (g)	0.0%	6.1%	7.2%	2.7%	7.7%	0.0%
TERMINAL (d)	0/24 (0%)	0/16 (0%)	1/28 (4%)	0/21 (0%)	1/20 (5%)	0/21 (0%)
FIRST INCIDENCE	---	261	591	691	510	---
STATISTICAL TESTS						
LIFE TABLE	P=0.294N	P=0.235	P=0.144	P=0.485	P=0.111	(e)
POLY 3	P=0.312N	P=0.201	P=0.131	P=0.487	P=0.118	(e)
POLY 1.5	P=0.298N	P=0.214	P=0.126	P=0.489	P=0.119	(e)
POLY 6	P=0.325N	P=0.189	P=0.140	P=0.487	P=0.116	(e)
LOGISTIC REGRESSION	P=0.270N	P=0.492	P=0.122	P=0.486	P=0.120	(e)
COCH-ARM / FISHERS	P=0.277N	P=0.252	P=0.121	P=0.500	P=0.121	(e)
ORDER RESTRICTED	P=0.266	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Skin Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	2/54 (4%)	2/53 (4%)	0/53 (0%)	2/53 (4%)	0/51 (0%)
POLY-3 RATE (b)	0/39.01	2/32.88	2/41.39	0/36.33	2/39.06	0/33.11
POLY-3 PERCENT (g)	0.0%	6.1%	4.8%	0.0%	5.1%	0.0%
TERMINAL (d)	0/24 (0%)	0/16 (0%)	1/28 (4%)	0/21 (0%)	0/20 (0%)	0/21 (0%)
FIRST INCIDENCE	---	261	656	---	510	---
STATISTICAL TESTS						
LIFE TABLE	P=0.344N	P=0.235	P=0.277	(e)	P=0.235	(e)
POLY 3	P=0.370N	P=0.201	P=0.250	(e)	P=0.237	(e)
POLY 1.5	P=0.356N	P=0.214	P=0.245	(e)	P=0.238	(e)
POLY 6	P=0.382N	P=0.189	P=0.260	(e)	P=0.236	(e)
LOGISTIC REGRESSION	P=0.323N	P=0.492	P=0.250	(e)	P=0.238	(e)
COCH-ARM / FISHERS	P=0.335N	P=0.252	P=0.248	(e)	P=0.248	(e)
ORDER RESTRICTED	P=0.328N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Thyroid Gland: C-Cell Adenoma						
TUMOR RATES						
OVERALL (a)	16/51 (31%)	13/52 (25%)	17/53 (32%)	12/53 (23%)	22/53 (42%)	7/51 (14%)
POLY-3 RATE (b)	16/39.99	13/32.09	17/43.11	12/38.16	22/40.39	7/33.34
POLY-3 PERCENT (g)	40.0%	40.5%	39.4%	31.5%	54.5%	21.0%
TERMINAL (d)	10/24 (42%)	10/16 (63%)	11/28 (39%)	7/21 (33%)	15/20 (75%)	6/21 (29%)
FIRST INCIDENCE	555	438	443	528	555	668
STATISTICAL TESTS						
LIFE TABLE	P=0.075N	P=0.378	P=0.478N	P=0.373N	P=0.063	P=0.069N
POLY 3	P=0.090N	P=0.581	P=0.569N	P=0.285N	P=0.129	P=0.062N
POLY 1.5	P=0.065N	P=0.500N	P=0.583N	P=0.271N	P=0.157	P=0.045N*
POLY 6	P=0.131N	P=0.470	P=0.545N	P=0.297N	P=0.099	P=0.085N
LOGISTIC REGRESSION	P=0.070N	P=0.510	P=0.562N	P=0.296N	P=0.121	P=0.064N
COCH-ARM / FISHERS	P=0.049N*	P=0.309N	P=0.553	P=0.217N	P=0.192	P=0.028N*
ORDER RESTRICTED	P=0.051N	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Thyroid Gland: C-Cell Carcinoma						
TUMOR RATES						
OVERALL (a)	2/51 (4%)	2/52 (4%)	1/53 (2%)	1/53 (2%)	2/53 (4%)	0/51 (0%)
POLY-3 RATE (b)	2/38.11	2/30.30	1/41.12	1/36.64	2/38.33	0/33.11
POLY-3 PERCENT (g)	5.3%	6.6%	2.4%	2.7%	5.2%	0.0%
TERMINAL (d)	2/24 (8%)	2/16 (13%)	1/28 (4%)	0/21 (0%)	2/20 (10%)	0/21 (0%)
FIRST INCIDENCE	731 (T)	731 (T)	731 (T)	647	731 (T)	---
STATISTICAL TESTS						
LIFE TABLE	P=0.223N	P=0.542	P=0.446N	P=0.527N	P=0.630	P=0.267N
POLY 3	P=0.238N	P=0.609	P=0.473N	P=0.514N	P=0.693N	P=0.269N
POLY 1.5	P=0.226N	P=0.641	P=0.478N	P=0.509N	P=0.686N	P=0.258N
POLY 6	P=0.253N	P=0.579	P=0.464N	P=0.515N	P=0.690	P=0.278N
LOGISTIC REGRESSION	P=0.225N	P=0.542	P=0.446N	P=0.521N	P=0.630	(e)
COCH-ARM / FISHERS	P=0.209N	P=0.684N	P=0.485N	P=0.485N	P=0.676N	P=0.248N
ORDER RESTRICTED	P=0.169N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Thyroid Gland: C-Cell Carcinoma or Adenoma						
TUMOR RATES						
OVERALL (a)	18/51 (35%)	15/52 (29%)	18/53 (34%)	13/53 (25%)	23/53 (43%)	7/51 (14%)
POLY-3 RATE (b)	18/39.99	15/32.09	18/43.11	13/38.46	23/40.39	7/33.34
POLY-3 PERCENT (g)	45.0%	46.8%	41.8%	33.8%	57.0%	21.0%
TERMINAL (d)	12/24 (50%)	12/16 (75%)	12/28 (43%)	7/21 (33%)	16/20 (80%)	6/21 (29%)
FIRST INCIDENCE	555	438	443	528	555	668
STATISTICAL TESTS						
LIFE TABLE	P=0.032N*	P=0.308	P=0.382N	P=0.309N	P=0.081	P=0.028N*
POLY 3	P=0.038N*	P=0.538	P=0.468N	P=0.209N	P=0.185	P=0.023N*
POLY 1.5	P=0.027N*	P=0.526N	P=0.487N	P=0.203N	P=0.219	P=0.016N*
POLY 6	P=0.060N	P=0.408	P=0.437N	P=0.208N	P=0.146	P=0.033N*
LOGISTIC REGRESSION	P=0.028N*	P=0.435	P=0.460N	P=0.233N	P=0.167	P=0.026N*
COCH-ARM / FISHERS	P=0.021N*	P=0.312N	P=0.525N	P=0.162N	P=0.260	P=0.010N*
ORDER RESTRICTED	P=0.018N*	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Uterus Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	1/54 (2%)	2/53 (4%)	0/53 (0%)	1/53 (2%)	0/51 (0%)
POLY-3 RATE (b)	0/39.01	1/31.14	2/41.96	0/36.33	1/38.34	0/33.11
POLY-3 PERCENT (g)	0.0%	3.2%	4.8%	0.0%	2.6%	0.0%
TERMINAL (d)	0/24 (0%)	0/16 (0%)	0/28 (0%)	0/21 (0%)	0/20 (0%)	0/21 (0%)
FIRST INCIDENCE	---	696	527	---	729	---
STATISTICAL TESTS						
LIFE TABLE	P=0.399N	P=0.423	P=0.262	(e)	P=0.473	(e)
POLY 3	P=0.384N	P=0.455	P=0.253	(e)	P=0.497	(e)
POLY 1.5	P=0.379N	P=0.472	P=0.247	(e)	P=0.499	(e)
POLY 6	P=0.388N	P=0.442	P=0.265	(e)	P=0.494	(e)
LOGISTIC REGRESSION	P=0.382N	P=0.442	P=0.220	(e)	P=0.482	(e)
COCH-ARM / FISHERS	P=0.376N	P=0.505	P=0.248	(e)	P=0.500	(e)
ORDER RESTRICTED	P=0.365N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Uterus Leiomyosarcoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	0/54 (0%)	0/53 (0%)	3/53 (6%)	0/53 (0%)	0/51 (0%)
POLY-3 RATE (b)	0/39.01	0/31.01	0/41.12	3/36.33	0/38.33	0/33.11
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	8.3%	0.0%	0.0%
TERMINAL (d)	0/24 (0%)	0/16 (0%)	0/28 (0%)	3/21 (14%)	0/20 (0%)	0/21 (0%)
FIRST INCIDENCE	---	---	---	731 (T)	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.450N	(e)	(e)	P=0.096	(e)	(e)
POLY 3	P=0.454N	(e)	(e)	P=0.105	(e)	(e)
POLY 1.5	P=0.451N	(e)	(e)	P=0.108	(e)	(e)
POLY 6	P=0.460N	(e)	(e)	P=0.103	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.096	(e)	(e)
COCH-ARM / FISHERS	P=0.444N	(e)	(e)	P=0.121	(e)	(e)
ORDER RESTRICTED	P=0.276	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
Uterus Polyp Stromal						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	7/53 (13%)	9/54 (17%)	4/53 (8%)	6/53 (11%)	3/53 (6%)	2/51 (4%)
POLY-3 RATE (b)	7/39.74	9/32.68	4/41.73	6/37.10	3/39.40	2/33.11
POLY-3 PERCENT (g)	17.6%	27.5%	9.6%	16.2%	7.6%	6.0%
TERMINAL (d)	4/24 (17%)	5/16 (31%)	3/28 (11%)	3/21 (14%)	1/20 (5%)	2/21 (10%)
FIRST INCIDENCE	590	590	530	647	467	731 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.047N*	P=0.148	P=0.201N	P=0.578N	P=0.209N	P=0.129N
POLY 3	P=0.051N	P=0.232	P=0.230N	P=0.554N	P=0.156N	P=0.126N
POLY 1.5	P=0.044N*	P=0.285	P=0.242N	P=0.545N	P=0.156N	P=0.112N
POLY 6	P=0.060N	P=0.197	P=0.213N	P=0.556N	P=0.159N	P=0.140N
LOGISTIC REGRESSION	P=0.041N*	P=0.189	P=0.226N	P=0.558N	P=0.163N	P=0.129N
COCH-ARM / FISHERS	P=0.037N*	P=0.409	P=0.263N	P=0.500N	P=0.160N	P=0.090N
ORDER RESTRICTED	P=0.035N*	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Uterus						
Squamous Cell Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	1/54 (2%)	2/53 (4%)	0/53 (0%)	0/53 (0%)	0/51 (0%)
POLY-3 RATE (b)	0/39.01	1/31.22	2/41.12	0/36.33	0/38.33	0/33.11
POLY-3 PERCENT (g)	0.0%	3.2%	4.9%	0.0%	0.0%	0.0%
TERMINAL (d)	0/24 (0%)	0/16 (0%)	2/28 (7%)	0/21 (0%)	0/20 (0%)	0/21 (0%)
FIRST INCIDENCE	---	675	731 (T)	---	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.312N	P=0.433	P=0.272	(e)	(e)	(e)
POLY 3	P=0.297N	P=0.456	P=0.249	(e)	(e)	(e)
POLY 1.5	P=0.297N	P=0.472	P=0.244	(e)	(e)	(e)
POLY 6	P=0.296N	P=0.443	P=0.256	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.312N	P=0.455	P=0.272	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.302N	P=0.505	P=0.248	(e)	(e)	(e)
ORDER RESTRICTED	P=0.296N	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Vagina						
Fibrosarcoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	2/54 (4%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	0/51 (0%)
POLY-3 RATE (b)	0/39.01	2/31.96	0/41.12	0/36.33	0/38.33	0/33.11
POLY-3 PERCENT (g)	0.0%	6.3%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	0/24 (0%)	1/16 (6%)	0/28 (0%)	0/21 (0%)	0/20 (0%)	0/21 (0%)
FIRST INCIDENCE	---	261	---	---	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.392N	P=0.196	(e)	(e)	(e)	(e)
POLY 3	P=0.441N	P=0.195	(e)	(e)	(e)	(e)
POLY 1.5	P=0.422N	P=0.210	(e)	(e)	(e)	(e)
POLY 6	P=0.460N	P=0.183	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.380N	P=0.323	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.390N	P=0.252	(e)	(e)	(e)	(e)
ORDER RESTRICTED	P=0.182N	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
Vagina Schwannoma Malignant						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	0/54 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	3/51 (6%)
POLY-3 RATE (b)	1/39.14	0/31.01	0/41.12	0/36.33	0/38.33	3/34.55
POLY-3 PERCENT (g)	2.6%	0.0%	0.0%	0.0%	0.0%	8.7%
TERMINAL (d)	0/24 (0%)	0/16 (0%)	0/28 (0%)	0/21 (0%)	0/20 (0%)	1/21 (5%)
FIRST INCIDENCE	696	---	---	---	---	442
STATISTICAL TESTS						
LIFE TABLE	P=0.006 **	P=0.577N	P=0.467N	P=0.539N	P=0.507N	P=0.253
POLY 3	P=0.007 **	P=0.546N	P=0.490N	P=0.515N	P=0.504N	P=0.260
POLY 1.5	P=0.007 **	P=0.529N	P=0.494N	P=0.512N	P=0.502N	P=0.270
POLY 6	P=0.007 **	P=0.561N	P=0.484N	P=0.517N	P=0.508N	P=0.255
LOGISTIC REGRESSION	P=0.008 **	P=0.558N	P=0.487N	P=0.515N	P=0.505N	P=0.311
COCH-ARM / FISHERS	P=0.007 **	P=0.495N	P=0.500N	P=0.500N	P=0.500N	P=0.294
ORDER RESTRICTED	P=0.006 **	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
All Organs Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	2/53 (4%)	0/54 (0%)	0/53 (0%)	0/53 (0%)	3/53 (6%)	0/51 (0%)
POLY-3 RATE (b)	2/39.53	0/31.01	0/41.12	0/36.33	3/39.68	0/33.11
POLY-3 PERCENT (g)	5.1%	0.0%	0.0%	0.0%	7.6%	0.0%
TERMINAL (d)	1/24 (4%)	0/16 (0%)	0/28 (0%)	0/21 (0%)	0/20 (0%)	0/21 (0%)
FIRST INCIDENCE	571	---	---	---	497	---
STATISTICAL TESTS						
LIFE TABLE	P=0.583N	P=0.318N	P=0.228N	P=0.269N	P=0.472	P=0.282N
POLY 3	P=0.591N	P=0.295N	P=0.228N	P=0.256N	P=0.502	P=0.278N
POLY 1.5	P=0.580N	P=0.272N	P=0.231N	P=0.252N	P=0.502	P=0.266N
POLY 6	P=0.603N	P=0.316N	P=0.222N	P=0.259N	P=0.500	P=0.287N
LOGISTIC REGRESSION	P=0.567N	P=0.265N	P=0.237N	P=0.245N	P=0.500	P=0.258N
COCH-ARM / FISHERS	P=0.569N	P=0.243N	P=0.248N	P=0.248N	P=0.500	P=0.257N
ORDER RESTRICTED	P=0.125N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
All Organs Benign Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	50/53 (94%)	41/54 (76%)	45/53 (85%)	46/53 (87%)	49/53 (92%)	40/51 (78%)
POLY-3 RATE (b)	50/51.13	41/44.71	45/50.28	46/48.45	49/50.80	40/45.55
POLY-3 PERCENT (g)	97.8%	91.7%	89.5%	94.9%	96.5%	87.8%
TERMINAL (d)	24/24 (100%)	16/16 (100%)	25/28 (89%)	19/21 (91%)	19/20 (95%)	18/21 (86%)
FIRST INCIDENCE	211	310	418	269	341	360
STATISTICAL TESTS						
LIFE TABLE	P=0.477N	P=0.260	P=0.086N	P=0.530	P=0.377	P=0.414N
POLY 3	P=0.118N	P=0.114N	P=0.063N	P=0.396N	P=0.598N	P=0.034N*
POLY 1.5	P=0.125N	P=0.042N*	P=0.073N	P=0.384N	P=0.566N	P=0.028N*
POLY 6	P=0.134N	P=0.236N	P=0.065N	P=0.316N	P=0.586N	P=0.048N*
LOGISTIC REGRESSION	P=0.212N	P=0.081N	P=0.076N	P=0.337N	P=0.483N	P=0.038N*
COCH-ARM / FISHERS	P=0.183N	P=0.007N**	P=0.101N	P=0.160N	P=0.500N	P=0.017N*
ORDER RESTRICTED	P=0.015N*	(e)	(e)	(e)	(e)	(e)

Dose	0 UG/KG	10 UG/KG	Females 100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
All Organs Malignant Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	12/53 (23%)	20/54 (37%)	16/53 (30%)	14/53 (26%)	14/53 (26%)	12/51 (24%)
POLY-3 RATE (b)	12/41.43	20/40.62	16/44.73	14/39.78	14/41.91	12/38.88
POLY-3 PERCENT (g)	29.0%	49.2%	35.8%	35.2%	33.4%	30.9%
TERMINAL (d)	7/24 (29%)	6/16 (38%)	7/28 (25%)	6/21 (29%)	6/20 (30%)	3/21 (14%)
FIRST INCIDENCE	442	250	443	222	452	79
STATISTICAL TESTS						
LIFE TABLE	P=0.299N	P=0.015 *	P=0.388	P=0.318	P=0.312	P=0.421
POLY 3	P=0.248N	P=0.042 *	P=0.327	P=0.356	P=0.419	P=0.523
POLY 1.5	P=0.237N	P=0.052	P=0.296	P=0.367	P=0.420	P=0.532
POLY 6	P=0.254N	P=0.036 *	P=0.380	P=0.354	P=0.410	P=0.535
LOGISTIC REGRESSION	P=0.221N	P=0.111	P=0.269	P=0.376	P=0.407	P=0.587N
COCH-ARM / FISHERS	P=0.230N	P=0.078	P=0.255	P=0.411	P=0.411	P=0.549
ORDER RESTRICTED	P=0.402N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
			Females			
All Organs Malignant and Benign Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	52/53 (98%)	51/54 (94%)	49/53 (92%)	48/53 (91%)	51/53 (96%)	48/51 (94%)
POLY-3 RATE (b)	52/52.21	51/51.54	49/51.80	48/50.38	51/52.14	48/50.33
POLY-3 PERCENT (g)	99.6%	99.0%	94.6%	95.3%	97.8%	95.4%
TERMINAL (d)	24/24 (100%)	16/16 (100%)	26/28 (93%)	19/21 (91%)	19/20 (95%)	19/21 (91%)
FIRST INCIDENCE	211	250	418	222	341	79
STATISTICAL TESTS						
LIFE TABLE	P=0.366	P=0.042 *	P=0.146N	P=0.521	P=0.380	P=0.335
POLY 3	P=0.327N	P=0.936N	P=0.146N	P=0.201N	P=0.527N	P=0.211N
POLY 1.5	P=0.400N	P=0.621N	P=0.145N	P=0.181N	P=0.528N	P=0.229N
POLY 6	P=0.284N	P=1.000N	P=0.181N	P=0.219N	P=0.510N	P=0.216N
LOGISTIC REGRESSION	P=0.561	P=0.615N	P=0.154N	P=0.184N	P=0.478N	P=0.306N
COCH-ARM / FISHERS	P=0.591	P=0.316N	P=0.181N	P=0.103N	P=0.500N	P=0.294N
ORDER RESTRICTED	P=0.145N	(e)	(e)	(e)	(e)	(e)

(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).

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB 153)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

FINAL#2 CONTROL VS. STOP

REASONS FOR REMOVAL:
25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:
INCLUDE 001 0 UG/KG
INCLUDE 007 3000 UG/KG STOP

NTP
LAB: Battelle Columbus
EXPERIMENT: 96021 TEST: 01
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD
Rats(SPRAGUE-DAWLEY)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB 153)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 09:24:23

NTP C#: C96021
CAS: 35065-27-1

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 Medulla
Bone Marrow
Brain
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Ovary
Pancreas
Parathyroid Gland
Pituitary Gland
Thyroid Gland

NTP
LAB: Battelle Columbus
EXPERIMENT: 96021 TEST: 01
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB 153)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/22/03
TIME: 09:24:23

NTP C#: C96021
CAS: 35065-27-1

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TOXIC EQUIVALENCY FACTOR EVALUATION (

Female Rats

Organ	Morphology
Adrenal Medulla	Pheochromocytoma Benign
	Pheochromocytoma: Benign, Complex, Malignant, NOS
Islets, Pancreatic	Carcinoma or Adenoma
Liver	Cholangioma
Mammary Gland	Adenoma
	Carcinoma
	Carcinoma or Adenoma
	Fibroadenoma
	Fibroma, Fibroadenoma or Adenoma
	Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Pituitary Gland: Pars Distalis or Unspecified Site	Adenoma
	Carcinoma or Adenoma
Skin	Fibroma
	Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma
	Fibrosarcoma
	Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma
Thyroid Gland: C-Cell	Adenoma
	Carcinoma
	Carcinoma or Adenoma
Thyroid Gland: Follicular Cell	Adenoma
Uterus	Polyp Stromal
All Organs	Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type
	Benign Tumors
	Malignant Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	Females 0 UG/KG	Females 3000 UG/ KG STOP
Adrenal Medulla Pheochromocytoma Benign		
TUMOR RATES		
OVERALL (a)	2/53 (4%)	6/50 (12%)
POLY-3 RATE (b)	2/39.13	6/37.40
POLY-3 PERCENT (g)	5.1%	16.0%
TERMINAL (d)	1/24 (4%)	2/20 (10%)
FIRST INCIDENCE	701	591
STATISTICAL TESTS		
LIFE TABLE		P=0.113
POLY 3		P=0.117
POLY 1.5		P=0.114
POLY 6		P=0.124
LOGISTIC REGRESSION		P=0.113
COCH-ARM / FISHERS		P=0.117
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	Females 3000 UG/ KG STOP
Adrenal Medulla Pheochromocytoma: Benign, Complex, Malignant, NOS		
TUMOR RATES		
OVERALL (a)	3/53 (6%)	6/50 (12%)
POLY-3 RATE (b)	3/39.55	6/37.40
POLY-3 PERCENT (g)	7.6%	16.0%
TERMINAL (d)	1/24 (4%)	2/20 (10%)
FIRST INCIDENCE	608	591
STATISTICAL TESTS		
LIFE TABLE		P=0.208
POLY 3		P=0.214
POLY 1.5		P=0.210
POLY 6		P=0.222
LOGISTIC REGRESSION		P=0.208
COCH-ARM / FISHERS		P=0.216
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
Islets, Pancreatic		
Carcinoma or Adenoma		
TUMOR RATES		
OVERALL (a)	1/53 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/39.01	2/36.65
POLY-3 PERCENT (g)	2.6%	5.5%
TERMINAL (d)	1/24 (4%)	1/20 (5%)
FIRST INCIDENCE	731 (T)	656
STATISTICAL TESTS		
LIFE TABLE		P=0.458
POLY 3		P=0.485
POLY 1.5		P=0.483
POLY 6		P=0.491
LOGISTIC REGRESSION		P=0.480
COCH-ARM / FISHERS		P=0.478
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
Liver		
Cholangioma		
TUMOR RATES		
OVERALL (a)	0/53 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/39.01	2/36.38
POLY-3 PERCENT (g)	0.0%	5.5%
TERMINAL (d)	0/24 (0%)	2/20 (10%)
FIRST INCIDENCE	---	731 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.198
POLY 3		P=0.228
POLY 1.5		P=0.228
POLY 6		P=0.229
LOGISTIC REGRESSION		P=0.198
COCH-ARM / FISHERS		P=0.233
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	Females 0 UG/KG	3000 UG/ KG STOP
Mammary Gland Adenoma		
TUMOR RATES	#	#
OVERALL (a)	2/53 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/39.01	0/36.38
POLY-3 PERCENT (g)	5.1%	0.0%
TERMINAL (d)	2/24 (8%)	0/20 (0%)
FIRST INCIDENCE	731 (T)	---
STATISTICAL TESTS		
LIFE TABLE		P=0.278N
POLY 3		P=0.260N
POLY 1.5		P=0.263N
POLY 6		P=0.254N
LOGISTIC REGRESSION		(e)
COCH-ARM / FISHERS		P=0.262N
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	3000 UG/ KG STOP
Mammary Gland Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	8/53 (15%)	10/50 (20%)
POLY-3 RATE (b)	8/39.57	10/38.41
POLY-3 PERCENT (g)	20.2%	26.0%
TERMINAL (d)	6/24 (25%)	4/20 (20%)
FIRST INCIDENCE	608	245
STATISTICAL TESTS		
LIFE TABLE		P=0.296
POLY 3		P=0.367
POLY 1.5		P=0.352
POLY 6		P=0.393
LOGISTIC REGRESSION		P=0.334
COCH-ARM / FISHERS		P=0.346
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
Mammary Gland Carcinoma or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	9/53 (17%)	10/50 (20%)
POLY-3 RATE (b)	9/39.57	10/38.41
POLY-3 PERCENT (g)	22.8%	26.0%
TERMINAL (d)	7/24 (29%)	4/20 (20%)
FIRST INCIDENCE	608	245
STATISTICAL TESTS		
LIFE TABLE		P=0.381
POLY 3		P=0.472
POLY 1.5		P=0.453
POLY 6		P=0.502
LOGISTIC REGRESSION		P=0.432
COCH-ARM / FISHERS		P=0.444
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
Mammary Gland Fibroadenoma		
TUMOR RATES	#	#
OVERALL (a)	41/53 (77%)	30/50 (60%)
POLY-3 RATE (b)	41/49.26	30/43.00
POLY-3 PERCENT (g)	83.2%	69.8%
TERMINAL (d)	19/24 (79%)	11/20 (55%)
FIRST INCIDENCE	399	360
STATISTICAL TESTS		
LIFE TABLE		P=0.195N
POLY 3		P=0.091N
POLY 1.5		P=0.077N
POLY 6		P=0.096N
LOGISTIC REGRESSION		P=0.052N
COCH-ARM / FISHERS		P=0.045N*
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

	Females	
Dose	0 UG/KG	3000 UG/ KG STOP
Mammary Gland Fibroma, Fibroadenoma or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	41/53 (77%)	30/50 (60%)
POLY-3 RATE (b)	41/49.26	30/43.00
POLY-3 PERCENT (g)	83.2%	69.8%
TERMINAL (d)	19/24 (79%)	11/20 (55%)
FIRST INCIDENCE	399	360
STATISTICAL TESTS		
LIFE TABLE		P=0.195N
POLY 3		P=0.091N
POLY 1.5		P=0.077N
POLY 6		P=0.096N
LOGISTIC REGRESSION		P=0.052N
COCH-ARM / FISHERS		P=0.045N*
ORDER RESTRICTED		(e)

	Females	
Dose	0 UG/KG	3000 UG/ KG STOP
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	43/53 (81%)	37/50 (74%)
POLY-3 RATE (b)	43/49.39	37/44.76
POLY-3 PERCENT (g)	87.1%	82.7%
TERMINAL (d)	20/24 (83%)	14/20 (70%)
FIRST INCIDENCE	399	245
STATISTICAL TESTS		
LIFE TABLE		P=0.468N
POLY 3		P=0.378N
POLY 1.5		P=0.358N
POLY 6		P=0.367N
LOGISTIC REGRESSION		P=0.307N
COCH-ARM / FISHERS		P=0.264N
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma		
TUMOR RATES		
OVERALL (a)	18/53 (34%)	23/50 (46%)
POLY-3 RATE (b)	18/41.75	23/39.65
POLY-3 PERCENT (g)	43.1%	58.0%
TERMINAL (d)	10/24 (42%)	14/20 (70%)
FIRST INCIDENCE	211	437
STATISTICAL TESTS		
LIFE TABLE		P=0.107
POLY 3		P=0.120
POLY 1.5		P=0.117
POLY 6		P=0.131
LOGISTIC REGRESSION		P=0.125
COCH-ARM / FISHERS		P=0.148
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma		
TUMOR RATES		
OVERALL (a)	18/53 (34%)	24/50 (48%)
POLY-3 RATE (b)	18/41.75	24/40.16
POLY-3 PERCENT (g)	43.1%	59.8%
TERMINAL (d)	10/24 (42%)	14/20 (70%)
FIRST INCIDENCE	211	437
STATISTICAL TESTS		
LIFE TABLE		P=0.080
POLY 3		P=0.088
POLY 1.5		P=0.082
POLY 6		P=0.103
LOGISTIC REGRESSION		P=0.087
COCH-ARM / FISHERS		P=0.106
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	Females 0 UG/KG	 3000 UG/ KG STOP
Skin Fibroma		
TUMOR RATES	#	#
OVERALL (a)	0/53 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/39.01	2/37.14
POLY-3 PERCENT (g)	0.0%	5.4%
TERMINAL (d)	0/24 (0%)	1/20 (5%)
FIRST INCIDENCE	---	452
STATISTICAL TESTS		
LIFE TABLE		P=0.213
POLY 3		P=0.231
POLY 1.5		P=0.230
POLY 6		P=0.233
LOGISTIC REGRESSION		P=0.233
COCH-ARM / FISHERS		P=0.233
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	 3000 UG/ KG STOP
Skin Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma		
TUMOR RATES	#	#
OVERALL (a)	0/53 (0%)	7/50 (14%)
POLY-3 RATE (b)	0/39.01	7/38.88
POLY-3 PERCENT (g)	0.0%	18.0%
TERMINAL (d)	0/24 (0%)	2/20 (10%)
FIRST INCIDENCE	---	183
STATISTICAL TESTS		
LIFE TABLE		P=0.008 **
POLY 3		P=0.007 **
POLY 1.5		P=0.006 **
POLY 6		P=0.008 **
LOGISTIC REGRESSION		P=0.009 **
COCH-ARM / FISHERS		P=0.005 **
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	Females 3000 UG/ KG STOP
Skin		
Fibrosarcoma		
TUMOR RATES	#	#
OVERALL (a)	0/53 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/39.01	4/37.78
POLY-3 PERCENT (g)	0.0%	10.6%
TERMINAL (d)	0/24 (0%)	1/20 (5%)
FIRST INCIDENCE	---	183
STATISTICAL TESTS		
LIFE TABLE		P=0.054
POLY 3		P=0.056
POLY 1.5		P=0.055
POLY 6		P=0.058
LOGISTIC REGRESSION		P=0.063
COCH-ARM / FISHERS		P=0.052
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	Females 3000 UG/ KG STOP
Skin		
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma		
TUMOR RATES	#	#
OVERALL (a)	0/53 (0%)	5/50 (10%)
POLY-3 RATE (b)	0/39.01	5/38.11
POLY-3 PERCENT (g)	0.0%	13.1%
TERMINAL (d)	0/24 (0%)	1/20 (5%)
FIRST INCIDENCE	---	183
STATISTICAL TESTS		
LIFE TABLE		P=0.030 *
POLY 3		P=0.028 *
POLY 1.5		P=0.027 *
POLY 6		P=0.030 *
LOGISTIC REGRESSION		P=0.032 *
COCH-ARM / FISHERS		P=0.024 *
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
Thyroid Gland: C-Cell Adenoma		
TUMOR RATES		
OVERALL (a)	16/51 (31%)	18/49 (37%)
POLY-3 RATE (b)	16/39.99	18/37.75
POLY-3 PERCENT (g)	40.0%	47.7%
TERMINAL (d)	10/24 (42%)	11/20 (55%)
FIRST INCIDENCE	555	437
STATISTICAL TESTS		
LIFE TABLE		P=0.260
POLY 3		P=0.323
POLY 1.5		P=0.324
POLY 6		P=0.329
LOGISTIC REGRESSION		P=0.327
COCH-ARM / FISHERS		P=0.361
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
Thyroid Gland: C-Cell Carcinoma		
TUMOR RATES		
OVERALL (a)	2/51 (4%)	3/49 (6%)
POLY-3 RATE (b)	2/38.11	3/36.14
POLY-3 PERCENT (g)	5.3%	8.3%
TERMINAL (d)	2/24 (8%)	1/20 (5%)
FIRST INCIDENCE	731 (T)	669
STATISTICAL TESTS		
LIFE TABLE		P=0.444
POLY 3		P=0.480
POLY 1.5		P=0.477
POLY 6		P=0.489
LOGISTIC REGRESSION		P=0.477
COCH-ARM / FISHERS		P=0.481
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
Thyroid Gland: C-Cell Carcinoma or Adenoma		
TUMOR RATES		
OVERALL (a)	18/51 (35%)	19/49 (39%)
POLY-3 RATE (b)	18/39.99	19/37.90
POLY-3 PERCENT (g)	45.0%	50.1%
TERMINAL (d)	12/24 (50%)	11/20 (55%)
FIRST INCIDENCE	555	437
STATISTICAL TESTS		
LIFE TABLE		P=0.317
POLY 3		P=0.410
POLY 1.5		P=0.404
POLY 6		P=0.430
LOGISTIC REGRESSION		P=0.406
COCH-ARM / FISHERS		P=0.439
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
Thyroid Gland: Follicular Cell Adenoma		
TUMOR RATES		
OVERALL (a)	0/51 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/38.11	2/35.75
POLY-3 PERCENT (g)	0.0%	5.6%
TERMINAL (d)	0/24 (0%)	2/20 (10%)
FIRST INCIDENCE	---	731 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.198
POLY 3		P=0.229
POLY 1.5		P=0.229
POLY 6		P=0.230
LOGISTIC REGRESSION		P=0.198
COCH-ARM / FISHERS		P=0.238
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
Uterus		
Polyp Stromal		
TUMOR RATES	#	#
OVERALL (a)	7/53 (13%)	4/50 (8%)
POLY-3 RATE (b)	7/39.74	4/37.16
POLY-3 PERCENT (g)	17.6%	10.8%
TERMINAL (d)	4/24 (17%)	1/20 (5%)
FIRST INCIDENCE	590	624
STATISTICAL TESTS		
LIFE TABLE		P=0.324N
POLY 3		P=0.301N
POLY 1.5		P=0.309N
POLY 6		P=0.287N
LOGISTIC REGRESSION		P=0.297N
COCH-ARM / FISHERS		P=0.298N
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
All Organs		
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type		
TUMOR RATES	#	#
OVERALL (a)	2/53 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/39.53	0/36.38
POLY-3 PERCENT (g)	5.1%	0.0%
TERMINAL (d)	1/24 (4%)	0/20 (0%)
FIRST INCIDENCE	571	---
STATISTICAL TESTS		
LIFE TABLE		P=0.263N
POLY 3		P=0.265N
POLY 1.5		P=0.266N
POLY 6		P=0.263N
LOGISTIC REGRESSION		P=0.252N
COCH-ARM / FISHERS		P=0.262N
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
All Organs		
Benign Tumors		
TUMOR RATES	#	#
OVERALL (a)	50/53 (94%)	44/50 (88%)
POLY-3 RATE (b)	50/51.13	44/45.72
POLY-3 PERCENT (g)	97.8%	96.2%
TERMINAL (d)	24/24 (100%)	19/20 (95%)
FIRST INCIDENCE	211	360
STATISTICAL TESTS		
LIFE TABLE		P=0.520N
POLY 3		P=0.593N
POLY 1.5		P=0.520N
POLY 6		P=0.561N
LOGISTIC REGRESSION		P=0.341N
COCH-ARM / FISHERS		P=0.216N
ORDER RESTRICTED		(e)

Dose	Females 0 UG/KG	Females 3000 UG/KG STOP
All Organs		
Malignant Tumors		
TUMOR RATES	#	#
OVERALL (a)	12/53 (23%)	23/50 (46%)
POLY-3 RATE (b)	12/41.43	23/43.60
POLY-3 PERCENT (g)	29.0%	52.8%
TERMINAL (d)	7/24 (29%)	7/20 (35%)
FIRST INCIDENCE	442	183
STATISTICAL TESTS		
LIFE TABLE		P=0.017 *
POLY 3		P=0.018 *
POLY 1.5		P=0.014 *
POLY 6		P=0.026 *
LOGISTIC REGRESSION		P=0.012 *
COCH-ARM / FISHERS		P=0.011 *
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (
Terminal Sacrifice at 105 weeks

Dose	Females 0 UG/KG	3000 UG/ KG STOP
All Organs Malignant and Benign Tumors		
TUMOR RATES	#	#
OVERALL (a)	52/53 (98%)	49/50 (98%)
POLY-3 RATE (b)	52/52.21	49/50.00
POLY-3 PERCENT (g)	99.6%	98.0%
TERMINAL (d)	24/24 (100%)	19/20 (95%)
FIRST INCIDENCE	211	183
STATISTICAL TESTS		
LIFE TABLE		P=0.420
POLY 3		P=0.581N
POLY 1.5		P=0.658N
POLY 6		P=0.518N
LOGISTIC REGRESSION		P=0.763N
COCH-ARM / FISHERS		P=0.738N
ORDER RESTRICTED		(e)

(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]
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB 153)

FINAL#2

Facility: Battelle Columbus Laboratory

Chemical CAS #: 35065-27-1

Lock Date: 01/16/02

Cage Range: All

Reasons For Removal: 25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

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]
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB 153)

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
DISPOSITION SUMMARY						
Animals Initially In Study	98	86	98	98	98	80
Early Deaths						
Natural Death	11	15	8	9	15	11
Moribund Sacrifice	18	23	17	22	18	19
Dosing Accident				1		
Survivors						
Terminal Sacrifice	24	16	28	20	20	21
Natural Death				1		
Animals Examined Microscopically	53	54	53	53	53	51
ALIMENTARY SYSTEM						
Esophagus	(53)	(54)	(53)	(53)	(53)	(51)
Muscularis, Inflammation		3 [2.0]		1 [2.0]	2 [2.0]	1 [2.0]
Periesophageal Tissue, Hemorrhage				1 [3.0]		
Periesophageal Tissue, Inflammation				1 [2.0]		
Intestine Large, Colon	(53)	(54)	(53)	(53)	(53)	(50)
Inflammation, Chronic Active						1 [3.0]
Parasite Metazoan		1	1		1	2
Intestine Large, Rectum	(53)	(54)	(53)	(53)	(53)	(50)
Inflammation, Chronic Active						1 [3.0]
Parasite Metazoan	1	2	3	7	5	5
Intestine Large, Cecum	(53)	(54)	(53)	(53)	(53)	(50)
Inflammation, Chronic Active						1 [3.0]
Intestine Small, Duodenum	(53)	(54)	(53)	(53)	(53)	(51)
Parasite Metazoan						1
Intestine Small, Jejunum	(53)	(54)	(53)	(53)	(53)	(50)
Peyer's Patch, Hyperplasia, Lymphoid	1 [2.0]					1 [3.0]
Intestine Small, Ileum	(52)	(54)	(53)	(53)	(53)	(50)
Hyperplasia, Lymphoid	1 [3.0]					
Liver	(53)	(54)	(53)	(53)	(53)	(51)
Angiectasis	5 [1.8]	2 [2.5]	2 [1.0]	1 [1.0]	8 [1.9]	4 [1.5]
Basophilic Focus	8	5	16	6	3	8
Basophilic Focus, Multiple	8	12	9	7	7	2
Cholangiofibrosis					1 [2.0]	
Clear Cell Focus	3	3	4			2
Clear Cell Focus, Multiple	3	2	1			
Eosinophilic Focus	5	1	8	7	14	6
Eosinophilic Focus, Multiple	7	1	8	12	9	12
Fatty Change, Diffuse	3 [1.0]	7 [1.4]	2 [1.0]	11 [1.0]	21 [1.3]	17 [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)

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
ALIMENTARY SYSTEM - CONT						
Fatty Change, Focal	4 [1.0]		3 [1.0]	5 [1.2]	4 [1.0]	1 [1.0]
Hematopoietic Cell Proliferation	20 [1.1]	22 [1.1]	13 [1.1]	18 [1.3]	16 [1.0]	14 [1.2]
Hepatodiaphragmatic Nodule					1	1
Hyperplasia, Nodular					1	1
Inflammation	44 [1.2]	39 [1.2]	44 [1.1]	47 [1.1]	48 [1.1]	45 [1.3]
Mixed Cell Focus	8	3	7	6	5	3
Mixed Cell Focus, Multiple	21	16	22	19	19	12
Necrosis	7 [2.4]	7 [2.0]	7 [2.1]	5 [1.6]	12 [2.1]	10 [2.3]
Pigmentation	1 [1.0]	1 [1.0]	2 [1.5]	5 [1.6]	5 [1.2]	9 [1.0]
Bile Duct, Cyst	3 [2.7]	2 [2.0]	2 [2.5]	3 [2.0]	5 [2.6]	2 [2.5]
Bile Duct, Fibrosis	2 [1.0]	1 [1.0]	2 [1.5]	2 [1.0]	2 [1.0]	3 [1.0]
Bile Duct, Hyperplasia	5 [1.8]	3 [2.0]	2 [1.0]	14 [1.6]	10 [1.6]	17 [1.6]
Centrilobular, Degeneration	2 [2.0]	10 [2.4]	4 [2.3]	2 [2.0]	2 [2.0]	5 [2.0]
Hepatocyte, Hypertrophy		5 [1.2]	5 [1.4]	24 [1.4]	39 [2.0]	41 [2.3]
Oval Cell, Hyperplasia				1 [1.0]		4 [1.3]
Serosa, Fibrosis						1 [3.0]
Serosa, Inflammation			2 [3.0]			
Mesentery			(1)		(1)	
Fat, Inflammation, Chronic Active			1 [3.0]			
Oral Mucosa	(21)	(12)	(16)	(12)	(16)	(25)
Gingival, Hyperplasia, Squamous	21 [1.0]	10 [1.7]	16 [1.1]	11 [1.1]	16 [1.4]	25 [1.1]
Pancreas	(53)	(54)	(53)	(53)	(53)	(51)
Cyst			1 [2.0]			
Degeneration		1 [2.0]				
Inflammation, Chronic Active	2 [2.0]		1 [1.0]	1 [2.0]		2 [1.0]
Acinus, Atrophy	1 [1.0]		1 [2.0]	1 [2.0]		2 [1.5]
Acinus, Hyperplasia	3 [2.7]					
Acinus, Vacuolization Cytoplasmic				1 [1.0]	1 [1.0]	2 [1.5]
Salivary Glands	(51)	(52)	(53)	(52)	(53)	(51)
Ectopic Tissue				1		
Stomach, Forestomach	(53)	(54)	(53)	(53)	(53)	(51)
Hyperkeratosis		1 [2.0]			1 [2.0]	2 [2.0]
Hyperplasia, Squamous	3 [2.0]	4 [1.8]	2 [2.0]	6 [1.7]	4 [1.8]	4 [2.5]
Inflammation				3 [2.0]	3 [1.7]	2 [3.0]
Mineralization		1 [1.0]		2 [1.5]	2 [2.0]	
Ulcer				2 [3.0]	3 [2.0]	1 [2.0]
Serosa, Inflammation, Chronic Active			1 [3.0]			
Stomach, Glandular	(53)	(54)	(53)	(53)	(53)	(51)
Erosion	1 [2.0]		1 [2.0]	2 [2.0]		
Inflammation				2 [2.0]		
Mineralization	5 [1.8]	8 [1.3]	8 [1.3]	10 [1.5]	10 [1.5]	2 [1.5]
Tooth	(34)	(13)	(19)	(22)	(23)	(35)
Degeneration	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)

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
ALIMENTARY SYSTEM - CONT						
Peridontal Tissue, Inflammation	33 [1.2]	13 [1.4]	19 [1.1]	21 [1.2]	23 [1.4]	35 [1.3]
CARDIOVASCULAR SYSTEM						
Blood Vessel	(52)	(54)	(53)	(53)	(53)	(51)
Aorta, Mineralization	2 [2.0]	1 [2.0]		1 [2.0]	1 [2.0]	
Heart	(52)	(54)	(53)	(53)	(53)	(51)
Cardiomyopathy	22 [1.1]	18 [1.2]	19 [1.0]	19 [1.2]	23 [1.1]	24 [1.1]
Inflammation		2 [3.0]		1 [2.0]		1 [1.0]
Mineralization	1 [2.0]			1 [1.0]		
Necrosis		1 [3.0]				
Thrombosis		2 [3.0]				
ENDOCRINE SYSTEM						
Adrenal Cortex	(53)	(54)	(53)	(53)	(53)	(51)
Angiectasis	21 [1.9]	23 [1.7]	34 [1.8]	25 [1.6]	29 [1.6]	21 [1.9]
Atrophy				1 [2.0]	2 [2.0]	
Degeneration, Cystic	9 [2.1]	12 [2.2]	15 [2.3]	13 [2.2]	12 [2.0]	13 [1.8]
Hematopoietic Cell Proliferation		1 [1.0]		1 [1.0]		3 [1.3]
Hyperplasia	18 [2.4]	24 [2.4]	27 [2.6]	27 [2.4]	28 [2.4]	11 [2.5]
Hypertrophy	48 [2.1]	35 [1.9]	45 [1.8]	35 [1.9]	42 [1.9]	41 [2.0]
Inflammation				1 [1.0]		1 [1.0]
Mineralization				2 [2.0]	1 [2.0]	
Necrosis	1 [3.0]	2 [2.5]	1 [2.0]	2 [3.5]	3 [2.7]	3 [2.0]
Vacuolization Cytoplasmic	10 [1.3]	8 [1.5]	14 [1.5]	16 [1.8]	12 [1.5]	14 [1.6]
Adrenal Medulla	(53)	(54)	(53)	(53)	(53)	(51)
Angiectasis			1 [2.0]	1 [2.0]		
Hyperplasia	18 [2.1]	14 [2.1]	19 [1.9]	14 [2.3]	20 [2.1]	12 [1.9]
Islets, Pancreatic	(53)	(54)	(53)	(53)	(53)	(51)
Hyperplasia	1 [2.0]		1 [2.0]	1 [2.0]		
Parathyroid Gland	(49)	(46)	(50)	(47)	(46)	(48)
Angiectasis				1 [1.0]		
Cyst	1 [2.0]					
Fibrosis		1 [3.0]				
Hyperplasia	2 [1.5]			1 [2.0]		1 [2.0]
Pituitary Gland	(53)	(54)	(53)	(53)	(53)	(50)
Angiectasis	15 [2.0]	16 [2.5]	20 [2.5]	26 [2.2]	28 [2.4]	14 [2.3]
Atypia Cellular				1 [2.0]		
Cyst			1 [2.0]			1 [2.0]
Cytoplasmic Alteration	2 [1.5]		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)

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
ENDOCRINE SYSTEM - CONT						
Vacuolization Cytoplasmic					1 [1.0]	
Pars Distalis, Hyperplasia	23 [2.4]	18 [2.2]	22 [2.4]	16 [2.4]	23 [2.3]	25 [2.2]
Thyroid Gland	(51)	(52)	(53)	(53)	(53)	(51)
Angiectasis		1 [2.0]			1 [2.0]	
C-Cell, Hyperplasia	19 [1.9]	17 [2.1]	23 [2.0]	17 [1.6]	19 [1.9]	16 [1.9]
Follicular Cell, Hyperplasia	1 [2.0]				2 [2.0]	2 [1.5]
Follicular Cell, Hypertrophy	5 [2.0]	9 [1.7]	9 [1.9]	12 [1.7]	10 [2.1]	17 [1.8]
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(53)	(51)	(52)	(53)	(51)	(50)
Atrophy				1 [2.0]		
Inflammation	52 [1.6]	45 [1.9]	41 [1.8]	48 [1.6]	48 [1.6]	46 [1.4]
Inflammation, Chronic Active						1 [4.0]
Duct, Cyst	49 [2.3]	40 [2.5]	36 [2.4]	43 [2.4]	45 [2.3]	41 [2.3]
Ovary	(53)	(53)	(53)	(53)	(53)	(50)
Atrophy	47 [4.0]	43 [4.0]	42 [4.0]	38 [4.0]	44 [3.9]	39 [3.9]
Cyst	14 [2.2]	7 [2.3]	17 [2.2]	17 [2.2]	16 [2.3]	17 [2.2]
Inflammation, Chronic Active			2 [3.5]	1 [2.0]	5 [3.0]	7 [3.6]
Necrosis			1 [2.0]			
Interstitial Cell, Hyperplasia	1 [2.0]					1 [3.0]
Oviduct	(50)	(38)	(44)	(35)	(39)	(45)
Cyst		1 [2.0]	2 [3.0]	1 [2.0]	1 [3.0]	
Dilatation			1 [3.0]			1 [4.0]
Inflammation, Chronic Active	1 [3.0]		2 [2.5]	1 [3.0]	5 [3.2]	7 [3.3]
Uterus	(53)	(54)	(53)	(53)	(53)	(50)
Adenomyosis	2 [3.5]	1 [2.0]		1 [2.0]		1 [3.0]
Angiectasis		1 [3.0]			1 [3.0]	
Congestion				1 [1.0]		
Cyst			1 [3.0]	1 [3.0]		
Hemorrhage		2 [3.0]				
Inflammation, Chronic Active	2 [3.0]	1 [3.0]	5 [2.4]	4 [2.8]	2 [3.0]	8 [3.0]
Inflammation, Suppurative	5 [1.6]	6 [1.8]	6 [1.8]	2 [1.0]	16 [2.0]	8 [1.6]
Metaplasia, Squamous	23 [2.3]	29 [2.1]	27 [2.5]	17 [2.3]	27 [2.7]	32 [2.6]
Thrombosis				1 [3.0]	2 [3.0]	
Ulcer		1 [2.0]				
Cervix, Hyperplasia, Stromal	1 [3.0]				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]
TOXIC EQUIVALENCY FACTOR EVALUATION (PCB 153)

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
GENITAL SYSTEM - CONT						
Cervix, Inflammation, Suppurative	1 [3.0]					
Endometrium, Hyperplasia, Cystic	37 [2.4]	29 [2.1]	32 [2.4]	28 [2.3]	25 [2.2]	21 [2.1]
Endometrium, Hyperplasia, Stromal					1 [3.0]	
Vagina	(1)	(3)	(2)	(1)	(1)	(3)
Inflammation			1 [1.0]			
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(54)	(53)	(53)	(53)	(51)
Hyperplasia	34 [2.9]	41 [3.3]	40 [3.0]	38 [3.1]	42 [3.2]	46 [2.9]
Lymph Node	(3)	(3)	(3)	(2)	(5)	(6)
Hemorrhage			1 [2.0]			
Hyperplasia, Lymphoid			1 [3.0]			
Hyperplasia, Plasma Cell		1 [3.0]	1 [3.0]			
Iliac, Ectasia					1 [2.0]	
Iliac, Hyperplasia, Plasma Cell					1 [3.0]	
Lumbar, Ectasia		1 [3.0]	2 [3.0]			2 [2.5]
Lumbar, Hemorrhage			1 [2.0]			1 [2.0]
Lumbar, Hyperplasia, Histiocytic					1 [2.0]	
Lumbar, Hyperplasia, Plasma Cell					1 [3.0]	2 [2.0]
Mediastinal, Congestion	3 [2.0]					
Mediastinal, Ectasia						2 [2.0]
Mediastinal, Hyperplasia, Histiocytic	1 [2.0]					
Mediastinal, Hyperplasia, Lymphoid	1 [2.0]	1 [2.0]				
Mediastinal, Hyperplasia, Plasma Cell	1 [3.0]	1 [2.0]				
Renal, Ectasia						2 [3.5]
Renal, Hyperplasia, Plasma Cell						1 [2.0]
Renal, Inflammation, Chronic Active				1 [4.0]		
Lymph Node, Mandibular	(51)	(52)	(53)	(51)	(53)	(51)
Congestion					1 [2.0]	
Ectasia			1 [2.0]		1 [2.0]	1 [3.0]
Hemorrhage			1 [2.0]			
Hyperplasia, Lymphoid	1 [2.0]	1 [2.0]	2 [2.5]	1 [2.0]	3 [2.3]	1 [2.0]
Hyperplasia, Plasma Cell	37 [2.3]	36 [2.2]	30 [2.3]	33 [2.4]	37 [2.4]	38 [2.3]
Inflammation						1 [3.0]
Lymph Node, Mesenteric	(52)	(54)	(53)	(53)	(53)	(51)
Ectasia		1 [1.0]				
Hemorrhage	1 [2.0]					
Hyperplasia, Plasma Cell						1 [3.0]
Inflammation, Chronic Active						1 [4.0]
Spleen	(53)	(54)	(53)	(53)	(53)	(51)
Hematopoietic Cell Proliferation	46 [1.7]	48 [2.3]	52 [2.2]	48 [1.9]	46 [1.8]	47 [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)

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
HEMATOPOIETIC SYSTEM - CONT						
Hemorrhage						1 [3.0]
Infarct						1 [3.0]
Necrosis		1 [2.0]	1 [2.0]			1 [3.0]
Pigmentation	47 [1.5]	42 [1.5]	47 [1.6]	49 [1.4]	49 [1.5]	46 [1.4]
Lymphoid Follicle, Atrophy	1 [2.0]	6 [2.3]	2 [2.0]	3 [2.7]	3 [2.0]	3 [2.7]
Red Pulp, Atrophy				2 [2.5]		
Thymus	(48)	(53)	(52)	(53)	(53)	(47)
Atrophy	38 [2.6]	38 [2.7]	37 [2.7]	35 [2.6]	41 [2.7]	30 [2.6]
Cyst		1 [3.0]				1 [2.0]
Hemorrhage		3 [2.3]				
INTEGUMENTARY SYSTEM						
Mammary Gland	(53)	(54)	(53)	(53)	(53)	(51)
Cyst	2 [3.0]	1 [3.0]		2 [2.5]	1 [2.0]	3 [2.7]
Hyperplasia	22 [1.5]	23 [1.4]	32 [1.2]	27 [1.4]	32 [1.3]	22 [1.4]
Inflammation, Chronic Active			1 [3.0]			
Inflammation, Granulomatous		2 [2.0]	2 [2.0]	3 [1.7]		1 [2.0]
Skin	(53)	(54)	(53)	(53)	(53)	(51)
Cyst						1 [2.0]
Cyst Epithelial Inclusion		1			1	
Inflammation					1 [2.0]	
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
Brain	(53)	(54)	(53)	(53)	(53)	(51)
Hemorrhage	1 [3.0]		1 [2.0]	1 [2.0]	2 [3.0]	
Hydrocephalus				2 [2.0]	1 [1.0]	
Hyperplasia, Histiocytic				1 [3.0]		
Mineralization				1 [2.0]		
Necrosis	1 [3.0]			1 [2.0]		
Vacuolization Cytoplasmic						1 [2.0]
Glial Cell, Hyperplasia		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)

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
RESPIRATORY SYSTEM						
Lung	(52)	(54)	(53)	(53)	(53)	(51)
Congestion					1 [2.0]	
Hemorrhage	1 [2.0]					1 [1.0]
Infiltration Cellular, Histiocyte	45 [1.6]	40 [1.6]	40 [1.8]	40 [1.4]	27 [1.4]	28 [1.3]
Inflammation	6 [2.2]	7 [1.9]	2 [2.0]	6 [2.2]	7 [1.7]	9 [1.7]
Metaplasia, Squamous				1 [1.0]	1 [2.0]	1 [2.0]
Mineralization				1 [3.0]	1 [3.0]	
Alveolar Epithelium, Hyperplasia	20 [1.1]	21 [1.4]	16 [1.3]	11 [1.2]	9 [1.1]	6 [1.0]
Mediastinum, Hemorrhage				1 [3.0]		
Serosa, Inflammation, Chronic Active				1 [3.0]		
Nose	(53)	(54)	(53)	(53)	(53)	(51)
Cyst		1 [3.0]				
Inflammation	1 [1.0]	6 [2.0]	3 [2.0]	6 [1.5]	6 [1.8]	3 [2.0]
Goblet Cell, Hyperplasia			2 [2.5]	1 [2.0]	2 [2.0]	
Nasolacrimal Duct, Inflammation	2 [3.0]					2 [2.5]
Respiratory Epithelium, Hyperplasia			2 [2.0]		1 [2.0]	
Respiratory Epithelium, Mineralization		1 [2.0]				
Septum, Inflammation	4 [1.5]	3 [2.0]	5 [1.8]	3 [1.0]	7 [1.4]	6 [1.5]
Squamous Epithelium, Hyperplasia		1 [2.0]				
Turbinate, Inflammation	8 [1.1]	3 [1.7]	5 [1.4]	9 [1.4]	10 [1.7]	10 [1.5]
Trachea	(52)	(54)	(53)	(53)	(53)	(51)
Inflammation						1 [2.0]
SPECIAL SENSES SYSTEM						
Eye	(53)	(54)	(53)	(53)	(52)	(51)
Degeneration	1 [3.0]					
Anterior Chamber, Exudate					1 [2.0]	
Lens, Degeneration				1 [1.0]		
Retina, Atrophy	2 [1.5]		1 [1.0]		1 [1.0]	
Harderian Gland	(53)	(54)	(53)	(53)	(53)	(49)
Atrophy		1 [1.0]				
Inflammation	20 [1.0]	9 [1.1]	13 [1.1]	16 [1.1]	16 [1.1]	16 [1.2]
URINARY SYSTEM						
Kidney	(53)	(54)	(53)	(53)	(53)	(51)
Accumulation, Hyaline Droplet		3 [2.0]	1 [3.0]			1 [1.0]
Calculus Micro Observation Only	3	5	4	7	5	1
Casts Protein	3 [1.0]	2 [1.5]	2 [1.0]	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)

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	100 UG/KG	300 UG/KG	1000 UG/KG	3000 UG/KG
URINARY SYSTEM - CONT						
Cyst	1 [2.0]			1 [2.0]		
Degeneration			1 [2.0]			
Hydronephrosis			1 [3.0]		1 [3.0]	
Infarct	1 [3.0]		1 [3.0]	2 [2.5]		
Inflammation, Chronic Active		2 [1.0]			3 [1.7]	1 [1.0]
Inflammation, Suppurative	1 [1.0]	2 [2.0]	3 [1.0]	2 [1.0]	2 [1.0]	3 [2.0]
Mineralization	40 [1.1]	42 [1.1]	41 [1.0]	39 [1.1]	40 [1.1]	41 [1.0]
Necrosis		1 [3.0]				
Nephropathy	34 [1.1]	23 [1.1]	24 [1.0]	33 [1.1]	28 [1.2]	34 [1.1]
Pelvis, Dilatation		2 [2.5]				
Pelvis, Inflammation	1 [2.0]	4 [2.0]	2 [2.5]	4 [2.3]	5 [1.8]	4 [2.0]
Renal Tubule, Degeneration			1 [3.0]			1 [3.0]
Renal Tubule, Hyperplasia		1 [2.0]				
Transitional Epithelium, Hyperplasia	1 [2.0]	5 [1.8]	2 [2.5]	4 [2.0]	6 [1.8]	4 [2.3]
Ureter			(1)			
Cyst			1 [3.0]			
Urinary Bladder	(53)	(53)	(53)	(53)	(53)	(50)
Calculus Micro Observation Only		1				
Inflammation	8 [1.1]	11 [1.6]	6 [1.7]	8 [2.0]	13 [1.2]	9 [1.9]
Transitional Epithelium, Hyperplasia		3 [2.3]	2 [2.5]	3 [2.0]	2 [2.0]	3 [2.3]

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)

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
DISPOSITION SUMMARY	
Animals Initially In Study	50
Early Deaths	
Natural Death	14
Moribund Sacrifice	16
Survivors	
Terminal Sacrifice	20
Animals Examined Microscopically	50
ALIMENTARY SYSTEM	
Esophagus	(49)
Muscularis, Inflammation	3 [1.3]
Intestine Large, Rectum	(50)
Parasite Metazoan	3
Intestine Large, Cecum	(48)
Inflammation	1 [3.0]
Ulcer	1 [3.0]
Liver	(50)
Angiectasis	8 [1.6]
Basophilic Focus	8
Basophilic Focus, Multiple	2
Clear Cell Focus	1
Degeneration, Cystic	1 [2.0]
Eosinophilic Focus	4
Eosinophilic Focus, Multiple	10
Fatty Change, Diffuse	15 [1.1]
Fatty Change, Focal	6 [1.2]
Hematopoietic Cell Proliferation	17 [1.2]
Hepatodiaphragmatic Nodule	2
Hyperplasia, Histiocytic	1 [2.0]
Hyperplasia, Nodular	1
Inflammation	44 [1.1]
Mixed Cell Focus	7
Mixed Cell Focus, Multiple	13
Necrosis	9 [2.7]
Pigmentation	3 [1.3]
Bile Duct, Cyst	3 [2.0]
Bile Duct, Fibrosis	5 [1.2]
Bile Duct, Hyperplasia	12 [1.7]
Centrilobular, Degeneration	5 [2.2]

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)

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
ALIMENTARY SYSTEM - CONT	
Hepatocyte, Hypertrophy	32 [1.8]
Oval Cell, Hyperplasia	2 [1.0]
Oral Mucosa	(15)
Gingival, Hyperplasia, Squamous	15 [1.1]
Pancreas	(50)
Inflammation, Chronic Active	2 [1.0]
Acinus, Atrophy	3 [2.0]
Acinus, Hyperplasia	2 [2.0]
Acinus, Vacuolization Cytoplasmic	1 [2.0]
Salivary Glands	(48)
Inflammation, Chronic Active	1 [2.0]
Stomach, Forestomach	(50)
Hyperkeratosis	2 [2.0]
Hyperplasia, Squamous	5 [2.0]
Inflammation	4 [1.5]
Mineralization	3 [1.7]
Stomach, Glandular	(50)
Inflammation	1 [3.0]
Mineralization	3 [1.3]
Ulcer	1 [3.0]
Serosa, Inflammation	1 [2.0]
Tooth	(27)
Peridontal Tissue, Inflammation	27 [1.4]
CARDIOVASCULAR SYSTEM	
Heart	(50)
Cardiomyopathy	15 [1.1]
Epicardium, Inflammation	1 [1.0]
ENDOCRINE SYSTEM	
Adrenal Cortex	(50)
Angiectasis	20 [1.7]
Degeneration, Cystic	7 [1.7]
Hematopoietic Cell Proliferation	2 [1.5]
Hyperplasia	18 [2.3]
Hypertrophy	35 [1.8]
Necrosis	1 [2.0]
Vacuolization Cytoplasmic	12 [1.1]
Adrenal Medulla	(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)

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
ENDOCRINE SYSTEM - CONT	
Angiectasis	1 [2.0]
Hyperplasia	19 [2.2]
Parathyroid Gland	(45)
Hyperplasia	1 [2.0]
Pituitary Gland	(50)
Angiectasis	24 [2.3]
Pars Distalis, Hyperplasia	18 [2.4]
Rathke's Cleft, Pars Nervosa, Cyst	1 [2.0]
Thyroid Gland	(49)
C-Cell, Hyperplasia	13 [1.9]
Follicular Cell, Hypertrophy	12 [1.8]
GENERAL BODY SYSTEM	
None	
GENITAL SYSTEM	
Clitoral Gland	(48)
Inflammation	44 [1.5]
Duct, Cyst	41 [2.3]
Ovary	(49)
Atrophy	41 [3.9]
Cyst	16 [2.4]
Oviduct	(46)
Dilatation	1 [3.0]
Inflammation, Chronic Active	2 [3.0]
Uterus	(49)
Cyst	1 [4.0]
Inflammation, Chronic Active	1 [3.0]
Inflammation, Suppurative	9 [2.2]
Metaplasia, Squamous	24 [2.7]
Cervix, Cyst	1 [3.0]
Cervix, Hyperplasia, Stromal	2 [3.0]
Endometrium, Hyperplasia, Cystic	23 [1.8]
Vagina	(1)
Inflammation, Chronic Active	1 [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)

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
HEMATOPOIETIC SYSTEM - CONT	
Bone Marrow	(50)
Hyperplasia	40 [3.1]
Lymph Node	(1)
Mediastinal, Hemorrhage	1 [2.0]
Lymph Node, Mandibular	(48)
Ectasia	1 [2.0]
Hyperplasia, Lymphoid	1 [3.0]
Hyperplasia, Plasma Cell	37 [2.5]
Inflammation	1 [3.0]
Spleen	(50)
Accessory Spleen	1
Congestion	1 [3.0]
Hematopoietic Cell Proliferation	44 [1.9]
Hemorrhage	1 [2.0]
Pigmentation	50 [1.3]
Lymphoid Follicle, Atrophy	4 [2.3]
Thymus	(49)
Atrophy	29 [2.4]
Hemorrhage	1 [3.0]
Inflammation	1 [3.0]
Necrosis, Lymphoid	1 [2.0]
INTEGUMENTARY SYSTEM	
Mammary Gland	(50)
Cyst	3 [2.3]
Cyst, Multiple	1 [3.0]
Hyperplasia	27 [1.5]
Inflammation, Granulomatous	2 [1.5]
Skin	(50)
Ulcer	1 [4.0]
MUSCULOSKELETAL SYSTEM	
None	
NERVOUS SYSTEM	
None	

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)

SPRAGUE-DAWLEY RATS FEMALE	3000 UG/ KG STOP
RESPIRATORY SYSTEM	
Lung	(50)
Hemorrhage	1 [2.0]
Infiltration Cellular, Histiocyte	37 [1.3]
Inflammation	9 [1.8]
Alveolar Epithelium, Hyperplasia	4 [1.3]
Nose	(50)
Inflammation	2 [1.5]
Septum, Inflammation	4 [1.3]
Turbinate, Inflammation	5 [1.2]
SPECIAL SENSES SYSTEM	
Eye	(50)
Retina, Atrophy	2 [2.0]
Harderian Gland	(50)
Inflammation	15 [1.2]
URINARY SYSTEM	
Kidney	(50)
Casts Protein	4 [1.0]
Cyst	1 [2.0]
Fibrosis	1 [1.0]
Inflammation, Chronic Active	3 [2.7]
Inflammation, Suppurative	2 [2.0]
Mineralization	38 [1.0]
Nephropathy	22 [1.2]
Pelvis, Inflammation	3 [1.3]
Transitional Epithelium, Hyperplasia	4 [1.5]
Urinary Bladder	(49)
Inflammation	10 [1.7]
Transitional Epithelium, Hyperplasia	3 [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

National Toxicology Program

TR-521 Toxic Equivalency Factor Evaluation (TCDD)

Revised Pathology Tables – Female Rats Core Study

- **P03 - Incidence Rates of Non-Neoplastic Lesions**
- **P05 - Incidence Rates of Neoplasms by Anatomic Site (systemic lesions abridged)**
- **P08 - Statistical Analysis of Primary Tumors (control vs stop group)**
- **P08 - Statistical Analysis of Primary Tumors (control vs treated group)**
- **P18 - Incidence Rates of Non-Neoplastic Lesions**

Facility: Battelle Columbus Laboratory

Chemical CAS #: 1746-01-6

Lock Date: 06/28/01

Cage Range: All

Reasons For Removal:
25022 Accidently Killed
25019 Moribund Sacrifice
25021 Terminal Sacrifice
25018 Dosing Accident
25020 Natural Death

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)
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
DISPOSITION SUMMARY						
Animals Initially In Study	98	98	98	98	98	98
Early Deaths						
Moribund Sacrifice	19	27	15	19	17	17
Natural Death	9	6	10	15	14	15
Dosing Accident			5			
Survivors						
Terminal Sacrifice	25	21	23	19	22	21
Animals Examined Microscopically	53	54	53	53	53	53
ALIMENTARY SYSTEM						
Esophagus	(52)	(54)	(53)	(52)	(53)	(53)
Hemorrhage			1 (2%)			
Perforation			2 (4%)			
Muscularis, Inflammation	1 (2%)	2 (4%)	1 (2%)	1 (2%)	2 (4%)	
Periesophageal Tissue, Inflammation			3 (6%)			
Intestine Large, Colon	(52)	(53)	(53)	(53)	(53)	(51)
Parasite Metazoan	1 (2%)	2 (4%)	1 (2%)			2 (4%)
Intestine Large, Rectum	(52)	(54)	(53)	(52)	(53)	(53)
Parasite Metazoan	6 (12%)	4 (7%)			2 (4%)	1 (2%)
Intestine Small, Duodenum	(53)	(54)	(53)	(52)	(53)	(53)
Cyst						1 (2%)
Ulcer		1 (2%)				
Epithelium, Hyperplasia			1 (2%)			
Liver	(53)	(54)	(53)	(53)	(53)	(53)
Angiectasis	2 (4%)	1 (2%)	1 (2%)		3 (6%)	5 (9%)
Basophilic Focus	8 (15%)	6 (11%)	8 (15%)	7 (13%)	3 (6%)	3 (6%)
Basophilic Focus, Multiple	4 (8%)	3 (6%)	5 (9%)	1 (2%)	2 (4%)	5 (9%)
Cholangiofibrosis	1 (2%)	1 (2%)	2 (4%)	1 (2%)	11 (21%)	31 (58%)
Clear Cell Focus	4 (8%)	1 (2%)	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Clear Cell Focus, Multiple	1 (2%)			2 (4%)	1 (2%)	1 (2%)
Congestion	2 (4%)					2 (4%)
Cytoplasmic Alteration						2 (4%)
Degeneration, Cystic				2 (4%)		4 (8%)
Eosinophilic Focus	8 (15%)	6 (11%)	7 (13%)	10 (19%)	5 (9%)	2 (4%)
Eosinophilic Focus, Multiple	3 (6%)	8 (15%)	14 (26%)	17 (32%)	22 (42%)	42 (79%)
Fatty Change, Diffuse		2 (4%)	12 (23%)	17 (32%)	30 (57%)	48 (91%)
Fatty Change, Focal	2 (4%)	6 (11%)	4 (8%)	4 (8%)	1 (2%)	2 (4%)
Hematopoietic Cell Proliferation	1 (2%)	2 (4%)	2 (4%)	4 (8%)	2 (4%)	2 (4%)
Hemorrhage					1 (2%)	

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
ALIMENTARY SYSTEM - CONT						
Hepatodiaphragmatic Nodule		2 (4%)		1 (2%)	2 (4%)	
Hyperplasia, Nodular				3 (6%)	8 (15%)	37 (70%)
Inflammation	33 (62%)	46 (85%)	47 (89%)	50 (94%)	52 (98%)	49 (92%)
Mitotic Alteration				1 (2%)	1 (2%)	
Mixed Cell Focus	4 (8%)	8 (15%)	8 (15%)		2 (4%)	4 (8%)
Mixed Cell Focus, Multiple	26 (49%)	11 (20%)	21 (40%)	23 (43%)	28 (53%)	17 (32%)
Necrosis	1 (2%)	4 (7%)	4 (8%)	8 (15%)	10 (19%)	17 (32%)
Pigmentation	4 (8%)	9 (17%)	34 (64%)	48 (91%)	52 (98%)	53 (100%)
Thrombosis						1 (2%)
Toxic Hepatopathy		2 (4%)	8 (15%)	30 (57%)	45 (85%)	53 (100%)
Artery, Inflammation, Chronic Active						2 (4%)
Bile Duct, Cyst	3 (6%)	1 (2%)	2 (4%)	2 (4%)		21 (40%)
Bile Duct, Fibrosis		2 (4%)		1 (2%)	3 (6%)	4 (8%)
Bile Duct, Hyperplasia	5 (9%)	4 (7%)	7 (13%)	22 (42%)	40 (75%)	53 (100%)
Centrilobular, Degeneration	2 (4%)	2 (4%)		4 (8%)	3 (6%)	5 (9%)
Hepatocyte, Hypertrophy		19 (35%)	19 (36%)	42 (79%)	41 (77%)	52 (98%)
Hepatocyte, Multinucleated			16 (30%)	26 (49%)	36 (68%)	51 (96%)
Hepatocyte, Centrilobular, Atrophy					1 (2%)	
Oval Cell, Hyperplasia		4 (7%)	3 (6%)	20 (38%)	38 (72%)	53 (100%)
Portal, Fibrosis					5 (9%)	27 (51%)
Mesentery	(2)	(2)		(1)	(6)	(8)
Metaplasia, Osseous	1 (50%)					
Artery, Inflammation, Chronic Active		1 (50%)			4 (67%)	7 (88%)
Fat, Necrosis		1 (50%)		1 (100%)	1 (17%)	1 (13%)
Vein, Thrombosis	1 (50%)					
Oral Mucosa	(2)	(9)	(16)	(16)	(22)	(29)
Gingival, Hyperplasia, Squamous	1 (50%)	7 (78%)	14 (88%)	13 (81%)	15 (68%)	16 (55%)
Pancreas	(51)	(54)	(52)	(53)	(52)	(51)
Hemorrhage						1 (2%)
Inflammation, Acute				1 (2%)		
Inflammation, Chronic Active			2 (4%)	2 (4%)	3 (6%)	6 (12%)
Necrosis				1 (2%)		1 (2%)
Acinus, Atrophy	1 (2%)	2 (4%)	4 (8%)	4 (8%)	4 (8%)	9 (18%)
Acinus, Hyperplasia	2 (4%)			1 (2%)	2 (4%)	
Acinus, Vacuolization Cytoplasmic	1 (2%)			1 (2%)	15 (29%)	42 (82%)
Artery, Inflammation, Chronic Active		1 (2%)	1 (2%)	2 (4%)	2 (4%)	7 (14%)
Salivary Glands	(51)	(54)	(52)	(50)	(51)	(52)
Atrophy				2 (4%)	1 (2%)	
Inflammation			2 (4%)	3 (6%)		1 (2%)
Mineralization	1 (2%)					
Stomach, Forestomach	(53)	(54)	(53)	(53)	(53)	(53)
Cyst, Squamous			1 (2%)			
Edema				1 (2%)		1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
ALIMENTARY SYSTEM - CONT						
Erosion			1 (2%)		1 (2%)	
Hyperkeratosis	1 (2%)	1 (2%)	1 (2%)	1 (2%)	2 (4%)	3 (6%)
Hyperplasia, Squamous	3 (6%)	4 (7%)	4 (8%)	2 (4%)	7 (13%)	11 (21%)
Inflammation	1 (2%)	1 (2%)	2 (4%)		2 (4%)	5 (9%)
Mineralization			1 (2%)			
Necrosis						1 (2%)
Ulcer	2 (4%)	1 (2%)		1 (2%)	1 (2%)	4 (8%)
Stomach, Glandular	(53)	(54)	(53)	(53)	(53)	(53)
Diverticulum			1 (2%)			
Erosion	1 (2%)					
Metaplasia					1 (2%)	
Mineralization	3 (6%)			1 (2%)	3 (6%)	
Ulcer						2 (4%)
Tooth	(16)	(16)	(12)	(13)	(14)	(18)
Peridontal Tissue, Fibrosis	1 (6%)					
Peridontal Tissue, Inflammation	15 (94%)	16 (100%)	12 (100%)	13 (100%)	14 (100%)	18 (100%)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(53)	(54)	(53)	(53)	(53)	(53)
Thrombosis			1 (2%)			
Aorta, Mineralization	1 (2%)	1 (2%)			1 (2%)	
Heart	(53)	(54)	(53)	(52)	(53)	(52)
Cardiomyopathy	10 (19%)	12 (22%)	22 (42%)	25 (48%)	32 (60%)	36 (69%)
Mineralization	1 (2%)				1 (2%)	
Artery, Inflammation						1 (2%)
Artery, Mineralization		1 (2%)				
Artery, Thrombosis						1 (2%)
ENDOCRINE SYSTEM						
Adrenal Cortex	(53)	(54)	(53)	(53)	(53)	(53)
Angiectasis	11 (21%)	21 (39%)	18 (34%)	17 (32%)	17 (32%)	11 (21%)
Atrophy	2 (4%)		4 (8%)	5 (9%)	5 (9%)	27 (51%)
Degeneration, Cystic	11 (21%)	15 (28%)	21 (40%)	18 (34%)	17 (32%)	17 (32%)
Hyperplasia	16 (30%)	16 (30%)	18 (34%)	25 (47%)	29 (55%)	30 (57%)
Hypertrophy	41 (77%)	43 (80%)	46 (87%)	40 (75%)	45 (85%)	47 (89%)
Inflammation, Chronic Active	1 (2%)					
Inflammation, Suppurative	1 (2%)					
Mineralization						1 (2%)
Necrosis		1 (2%)	2 (4%)	1 (2%)	3 (6%)	1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
ENDOCRINE SYSTEM - CONT						
Thrombosis				1 (2%)		
Vacuolization Cytoplasmic	11 (21%)	7 (13%)	12 (23%)	21 (40%)	18 (34%)	15 (28%)
Adrenal Medulla	(53)	(54)	(53)	(53)	(53)	(53)
Angiectasis		1 (2%)	2 (4%)	1 (2%)		
Hyperplasia	19 (36%)	10 (19%)	18 (34%)	7 (13%)	10 (19%)	9 (17%)
Inflammation, Suppurative				1 (2%)		
Islets, Pancreatic	(51)	(54)	(53)	(53)	(52)	(52)
Hyperplasia			1 (2%)	1 (2%)		
Parathyroid Gland	(46)	(47)	(47)	(44)	(45)	(45)
Fibrosis			1 (2%)			
Hyperplasia	1 (2%)					
Pituitary Gland	(53)	(54)	(52)	(53)	(53)	(52)
Angiectasis	25 (47%)	18 (33%)	25 (48%)	20 (38%)	21 (40%)	9 (17%)
Atypia Cellular	1 (2%)					
Cyst	1 (2%)	1 (2%)				1 (2%)
Cytoplasmic Alteration	1 (2%)		1 (2%)	4 (8%)	3 (6%)	
Developmental Malformation	1 (2%)					
Inflammation, Chronic						1 (2%)
Vacuolization Cytoplasmic		3 (6%)	1 (2%)	2 (4%)	2 (4%)	
Pars Distalis, Hyperplasia	19 (36%)	19 (35%)	16 (31%)	21 (40%)	26 (49%)	19 (37%)
Pars Intermedia, Hyperplasia	2 (4%)				1 (2%)	1 (2%)
Thyroid Gland	(52)	(54)	(53)	(51)	(53)	(52)
Angiectasis		1 (2%)	1 (2%)	1 (2%)	4 (8%)	1 (2%)
Cyst	1 (2%)			1 (2%)		1 (2%)
Inflammation, Chronic Active			1 (2%)			
Inflammation, Suppurative			1 (2%)			
C-Cell, Hyperplasia	19 (37%)	17 (31%)	22 (42%)	19 (37%)	16 (30%)	23 (44%)
Follicular Cell, Hyperplasia	2 (4%)	2 (4%)				
Follicular Cell, Hypertrophy	3 (6%)	4 (7%)	4 (8%)	7 (14%)	10 (19%)	17 (33%)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(50)	(52)	(53)	(52)	(51)	(53)
Hyperplasia, Basal Cell	1 (2%)		1 (2%)			
Inflammation	41 (82%)	40 (77%)	35 (66%)	34 (65%)	28 (55%)	26 (49%)
Duct, Cyst	34 (68%)	37 (71%)	41 (77%)	42 (81%)	41 (80%)	48 (91%)
Ovary	(51)	(53)	(53)	(53)	(53)	(53)

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
GENITAL SYSTEM - CONT						
Atrophy	49 (96%)	46 (87%)	50 (94%)	44 (83%)	50 (94%)	31 (58%)
Congestion				1 (2%)		
Cyst	14 (27%)	16 (30%)	13 (25%)	15 (28%)	14 (26%)	13 (25%)
Fibrosis			1 (2%)		1 (2%)	
Inflammation, Chronic Active				1 (2%)		1 (2%)
Inflammation, Suppurative				1 (2%)	1 (2%)	
Artery, Inflammation, Chronic Active						1 (2%)
Corpus Luteum, Cyst		1 (2%)				
Periovarian Tissue, Inflammation, Suppurative				1 (2%)		
Oviduct	(2)	(1)	(2)		(1)	(1)
Inflammation	2 (100%)	1 (100%)	1 (50%)			1 (100%)
Necrosis					1 (100%)	
Epithelium, Hyperplasia			1 (50%)			
Uterus	(52)	(53)	(53)	(53)	(53)	(53)
Adenomyosis					1 (2%)	
Cyst						1 (2%)
Hemorrhage	1 (2%)					1 (2%)
Inflammation, Chronic Active		2 (4%)	3 (6%)		3 (6%)	1 (2%)
Inflammation, Suppurative	7 (13%)	6 (11%)	12 (23%)	9 (17%)	11 (21%)	5 (9%)
Metaplasia, Squamous	29 (56%)	31 (58%)	28 (53%)	23 (43%)	32 (60%)	17 (32%)
Necrosis				1 (2%)		
Ulcer			1 (2%)			
Cervix, Hyperplasia, Stromal		1 (2%)	1 (2%)	1 (2%)	1 (2%)	
Cervix, Inflammation, Suppurative					1 (2%)	
Endometrium, Adenomyosis			1 (2%)			
Endometrium, Hyperplasia, Cystic	30 (58%)	33 (62%)	35 (66%)	27 (51%)	31 (58%)	19 (36%)
Epithelium, Hyperplasia				1 (2%)		
Serosa, Inflammation, Chronic Active			1 (2%)			
Vagina		(1)	(1)	(3)	(3)	(1)
Cyst			1 (100%)		1 (33%)	
Hyperplasia, Stromal		1 (100%)				
Inflammation				2 (67%)		
Necrosis				1 (33%)		
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(54)	(53)	(53)	(53)	(53)
Atrophy						1 (2%)
Hyperplasia	36 (68%)	41 (76%)	32 (60%)	35 (66%)	37 (70%)	43 (81%)
Lymph Node	(2)	(6)	(3)	(5)	(6)	(9)
Deep Cervical, Hemorrhage				1 (20%)		
Inguinal, Ectasia					1 (17%)	

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
HEMATOPOIETIC SYSTEM - CONT						
Lumbar, Ectasia	1 (50%)	2 (33%)	1 (33%)	2 (40%)		
Lumbar, Hemorrhage				1 (20%)		
Lumbar, Hyperplasia, Plasma Cell		2 (33%)		1 (20%)		
Lumbar, Pigmentation				1 (20%)		
Mediastinal, Congestion					1 (17%)	
Mediastinal, Ectasia					1 (17%)	3 (33%)
Mediastinal, Hemorrhage		1 (17%)		1 (20%)		5 (56%)
Mediastinal, Hyperplasia					1 (17%)	
Mediastinal, Hyperplasia, Histiocytic			1 (33%)		1 (17%)	1 (11%)
Mediastinal, Hyperplasia, Lymphoid		1 (17%)				
Mediastinal, Hyperplasia, Plasma Cell				1 (20%)		
Mediastinal, Pigmentation			1 (33%)			1 (11%)
Renal, Ectasia		1 (17%)				
Renal, Hyperplasia, Histiocytic		1 (17%)				
Lymph Node, Mandibular	(51)	(54)	(52)	(50)	(51)	(52)
Congestion	1 (2%)					
Ectasia					1 (2%)	6 (12%)
Hyperplasia, Lymphoid		3 (6%)	3 (6%)			2 (4%)
Hyperplasia, Plasma Cell	25 (49%)	31 (57%)	23 (44%)	22 (44%)	15 (29%)	16 (31%)
Inflammation, Suppurative						1 (2%)
Lymph Node, Mesenteric	(52)	(53)	(53)	(53)	(53)	(51)
Atrophy		1 (2%)		1 (2%)		
Ectasia						1 (2%)
Hemorrhage					1 (2%)	
Hyperplasia, Histiocytic	1 (2%)				1 (2%)	2 (4%)
Hyperplasia, Plasma Cell					1 (2%)	
Spleen	(51)	(54)	(53)	(53)	(52)	(52)
Hematopoietic Cell Proliferation	46 (90%)	50 (93%)	38 (72%)	42 (79%)	44 (85%)	43 (83%)
Hyperplasia, Lymphoid	1 (2%)					4 (8%)
Necrosis			1 (2%)			
Pigmentation	45 (88%)	49 (91%)	49 (92%)	51 (96%)	49 (94%)	47 (90%)
Lymphoid Follicle, Atrophy	4 (8%)		1 (2%)		1 (2%)	1 (2%)
Thymus	(51)	(52)	(52)	(49)	(46)	(42)
Atrophy	36 (71%)	41 (79%)	44 (85%)	41 (84%)	44 (96%)	42 (100%)
Cyst					1 (2%)	1 (2%)
Hemorrhage	1 (2%)		1 (2%)			
Inflammation, Chronic Active					1 (2%)	
INTEGUMENTARY SYSTEM						
Mammary Gland	(53)	(54)	(53)	(53)	(53)	(53)
Cyst	4 (8%)	3 (6%)		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)
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
INTEGUMENTARY SYSTEM - CONT						
Hyperplasia	25 (47%)	21 (39%)	24 (45%)	22 (42%)	18 (34%)	16 (30%)
Inflammation, Chronic Active					1 (2%)	
Inflammation, Granulomatous	1 (2%)	1 (2%)	1 (2%)			1 (2%)
Skin	(53)	(54)	(53)	(53)	(53)	(53)
Cyst Epithelial Inclusion	1 (2%)					2 (4%)
Hemorrhage			1 (2%)			
Hyperplasia, Squamous			1 (2%)		1 (2%)	
Inflammation, Chronic Active			2 (4%)			1 (2%)
Necrosis			1 (2%)			
Ulcer			1 (2%)		1 (2%)	
Epidermis, Inflammation						1 (2%)
MUSCULOSKELETAL SYSTEM						
Bone	(53)	(54)	(53)	(53)	(53)	(53)
Fracture						1 (2%)
Maxilla, Inflammation, Focal, Suppurative		1 (2%)				
Skeletal Muscle			(1)	(2)		
Hemorrhage				1 (50%)		
Inflammation, Chronic Active				1 (50%)		
NERVOUS SYSTEM						
Brain	(53)	(54)	(53)	(53)	(53)	(53)
Hemorrhage			1 (2%)			
Hydrocephalus		1 (2%)	1 (2%)			
Inflammation, Suppurative					1 (2%)	
Mineralization		1 (2%)	1 (2%)		2 (4%)	2 (4%)
Vacuolization Cytoplasmic, Focal			1 (2%)			
Artery, Thrombosis					1 (2%)	
Cerebellum, Developmental Malformation	1 (2%)					
Cerebellum, Necrosis			1 (2%)			
Glial Cell, Hyperplasia		1 (2%)				1 (2%)
Spinal Cord			(1)			
Gliosis			1 (100%)			
RESPIRATORY SYSTEM						
Lung	(53)	(54)	(53)	(52)	(53)	(52)
Congestion			2 (4%)			

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
RESPIRATORY SYSTEM - CONT						
Edema			2 (4%)		1 (2%)	
Hemorrhage		1 (2%)				2 (4%)
Infiltration Cellular, Histiocyte	41 (77%)	46 (85%)	43 (81%)	43 (83%)	49 (92%)	50 (96%)
Inflammation, Chronic Active						1 (2%)
Inflammation, Granulomatous	2 (4%)	1 (2%)	2 (4%)	2 (4%)		
Inflammation, Suppurative	1 (2%)			2 (4%)		
Metaplasia, Squamous	1 (2%)				5 (9%)	6 (12%)
Mineralization	1 (2%)				1 (2%)	1 (2%)
Necrosis				1 (2%)		1 (2%)
Pigmentation		1 (2%)				
Alveolar Epithelium, Hyperplasia	12 (23%)					
Alveolar Epithelium, Metaplasia, Bronchiolar	2 (4%)	19 (35%)	33 (62%)	35 (67%)	45 (85%)	46 (88%)
Bronchiole, Dilatation			1 (2%)			
Serosa, Inflammation, Focal, Suppurative				1 (2%)		
Nose	(53)	(54)	(53)	(53)	(53)	(53)
Cyst, Squamous					1 (2%)	
Inflammation	2 (4%)			3 (6%)	5 (9%)	4 (8%)
Goblet Cell, Septum, Hyperplasia					1 (2%)	
Nasolacrimal Duct, Inflammation	2 (4%)					
Nasolacrimal Duct, Respiratory Epithelium, Hyperplasia					1 (2%)	
Nasopharyngeal Duct, Inflammation				1 (2%)		1 (2%)
Nasopharyngeal Duct, Necrosis				1 (2%)		
Olfactory Epithelium, Degeneration					1 (2%)	
Olfactory Epithelium, Inflammation					1 (2%)	1 (2%)
Respiratory Epithelium, Cyst					2 (4%)	
Respiratory Epithelium, Hyperplasia				1 (2%)	2 (4%)	
Septum, Hyperplasia, Squamous						1 (2%)
Septum, Inflammation						2 (4%)
Squamous Epithelium, Inflammation, Suppurative	1 (2%)					
Turbinate, Hyperplasia, Squamous						1 (2%)
Turbinate, Septum, Inflammation			1 (2%)	1 (2%)		2 (4%)
Turbinate, Respiratory Epithelium, Hyperplasia			1 (2%)	1 (2%)		
SPECIAL SENSES SYSTEM						
Eye	(53)	(54)	(53)	(52)	(53)	(53)
Degeneration	1 (2%)					
Hemorrhage	1 (2%)					
Anterior Chamber, 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)
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
SPECIAL SENSES SYSTEM - CONT						
Cornea, Inflammation, Suppurative			1 (2%)			1 (2%)
Lens, Degeneration					1 (2%)	
Retina, Atrophy	5 (9%)	5 (9%)	5 (9%)	3 (6%)	4 (8%)	6 (11%)
Retina, Degeneration					1 (2%)	
Harderian Gland	(53)	(54)	(53)	(52)	(53)	(53)
Atrophy, Focal	1 (2%)					
Inflammation	12 (23%)	3 (6%)	2 (4%)	2 (4%)	8 (15%)	6 (11%)
URINARY SYSTEM						
Kidney	(53)	(54)	(53)	(53)	(53)	(53)
Calculus Gross Observation						1 (2%)
Calculus Micro Observation Only	1 (2%)	1 (2%)	1 (2%)	3 (6%)	2 (4%)	
Casts Protein	3 (6%)	5 (9%)	2 (4%)		1 (2%)	1 (2%)
Cyst	2 (4%)				1 (2%)	1 (2%)
Fibrosis		1 (2%)				
Infarct			1 (2%)			
Inflammation, Chronic Active	5 (9%)	1 (2%)		1 (2%)	1 (2%)	
Inflammation, Suppurative			2 (4%)	1 (2%)	1 (2%)	2 (4%)
Mineralization	40 (75%)	39 (72%)	30 (57%)	32 (60%)	42 (79%)	42 (79%)
Necrosis				1 (2%)	1 (2%)	
Nephropathy	34 (64%)	26 (48%)	32 (60%)	36 (68%)	39 (74%)	52 (98%)
Papilla, Necrosis			1 (2%)			
Pelvis, Dilatation	2 (4%)	1 (2%)	1 (2%)		2 (4%)	
Pelvis, Inflammation	2 (4%)	1 (2%)	1 (2%)	1 (2%)	4 (8%)	2 (4%)
Renal Tubule, Degeneration						1 (2%)
Transitional Epithelium, Hyperplasia	3 (6%)	6 (11%)	8 (15%)	8 (15%)	11 (21%)	11 (21%)
Ureter	(1)					
Inflammation	1 (100%)					
Transitional Epithelium, Hyperplasia	1 (100%)					
Urinary Bladder	(52)	(53)	(53)	(52)	(53)	(53)
Calculus Micro Observation Only		1 (2%)				
Hemorrhage		1 (2%)				
Inflammation	6 (12%)	10 (19%)	4 (8%)		8 (15%)	3 (6%)
Metaplasia, Squamous						1 (2%)
Transitional Epithelium, Hyperplasia	1 (2%)	2 (4%)	1 (2%)		6 (11%)	2 (4%)

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

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
DISPOSITION SUMMARY	
Animals Initially In Study	50
Early Deaths	
Moribund Sacrifice	16
Natural Death	13
Survivors	
Terminal Sacrifice	21
Animals Examined Microscopically	50
ALIMENTARY SYSTEM	
Intestine Large, Colon	(49)
Parasite Metazoan	1 (2%)
Intestine Large, Rectum	(50)
Parasite Metazoan	5 (10%)
Intestine Small, Jejunum	(50)
Inflammation, Chronic	1 (2%)
Liver	(50)
Angiectasis	4 (8%)
Atypia Cellular	1 (2%)
Basophilic Focus	7 (14%)
Basophilic Focus, Multiple	9 (18%)
Cholangiofibrosis	1 (2%)
Clear Cell Focus	6 (12%)
Clear Cell Focus, Multiple	2 (4%)
Cytoplasmic Alteration	1 (2%)
Eosinophilic Focus	6 (12%)
Eosinophilic Focus, Multiple	21 (42%)
Fatty Change, Diffuse	10 (20%)
Fatty Change, Focal	8 (16%)
Hematopoietic Cell Proliferation	2 (4%)
Hepatodiaphragmatic Nodule	1 (2%)
Inflammation	43 (86%)
Mixed Cell Focus	1 (2%)
Mixed Cell Focus, Multiple	28 (56%)
Necrosis	8 (16%)
Pigmentation	45 (90%)
Toxic Hepatopathy	16 (32%)
Vacuolization Cytoplasmic	1 (2%)
Bile Duct, Cyst	6 (12%)
Bile Duct, Fibrosis	5 (10%)

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

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
ALIMENTARY SYSTEM - CONT	
Bile Duct, Hyperplasia	7 (14%)
Hepatocyte, Hypertrophy	22 (44%)
Hepatocyte, Multinucleated	32 (64%)
Oval Cell, Hyperplasia	1 (2%)
Portal, Fibrosis	1 (2%)
Serosa, Inflammation, Chronic Active	1 (2%)
Mesentery	(1)
Artery, Inflammation, Chronic Active	1 (100%)
Oral Mucosa	(11)
Gingival, Hyperplasia, Squamous	8 (73%)
Pancreas	(49)
Angiectasis	1 (2%)
Basophilic Focus	1 (2%)
Inflammation, Chronic Active	4 (8%)
Acinus, Atrophy	4 (8%)
Artery, Inflammation, Chronic Active	2 (4%)
Salivary Glands	(49)
Atrophy	2 (4%)
Fibrosis	1 (2%)
Inflammation	1 (2%)
Stomach, Forestomach	(50)
Hyperkeratosis	1 (2%)
Hyperplasia, Squamous	5 (10%)
Inflammation	4 (8%)
Ulcer	4 (8%)
Stomach, Glandular	(50)
Erosion	1 (2%)
Tongue	(1)
Inflammation, Chronic Active	1 (100%)
Tooth	(12)
Peridontal Tissue, Inflammation	12 (100%)
CARDIOVASCULAR SYSTEM	
Heart	(50)
Cardiomyopathy	22 (44%)
Inflammation	1 (2%)
Atrium, Thrombosis	2 (4%)
Epicardium, Inflammation, Chronic Active	1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
ENDOCRINE SYSTEM	
Adrenal Cortex	(50)
Angiectasis	15 (30%)
Atrophy	4 (8%)
Degeneration, Cystic	17 (34%)
Hyperplasia	20 (40%)
Hypertrophy	46 (92%)
Necrosis	3 (6%)
Vacuolization Cytoplasmic	13 (26%)
Adrenal Medulla	(50)
Hyperplasia	15 (30%)
Islets, Pancreatic	(49)
Hyperplasia	1 (2%)
Pituitary Gland	(50)
Angiectasis	15 (30%)
Cytoplasmic Alteration	1 (2%)
Vacuolization Cytoplasmic	3 (6%)
Pars Distalis, Hyperplasia	18 (36%)
Thyroid Gland	(49)
Angiectasis	1 (2%)
C-Cell, Hyperplasia	15 (31%)
Follicular Cell, Hypertrophy	6 (12%)
GENERAL BODY SYSTEM	
None	
GENITAL SYSTEM	
Clitoral Gland	(49)
Atrophy	1 (2%)
Hyperplasia, Basal Cell	1 (2%)
Hyperplasia, Squamous	1 (2%)
Inflammation	35 (71%)
Duct, Cyst	35 (71%)
Ovary	(49)
Atrophy	45 (92%)
Cyst	16 (33%)
Inflammation, Granulomatous	1 (2%)
Oviduct	(2)
Inflammation	2 (100%)

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

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
GENITAL SYSTEM - CONT	
Uterus	(50)
Inflammation, Chronic Active	1 (2%)
Inflammation, Suppurative	9 (18%)
Metaplasia, Squamous	33 (66%)
Cervix, Inflammation, Chronic Active	1 (2%)
Endometrium, Hyperplasia, Cystic	32 (64%)
HEMATOPOIETIC SYSTEM	
Bone Marrow	(50)
Atrophy	1 (2%)
Hyperplasia	36 (72%)
Myelofibrosis	1 (2%)
Lymph Node	(5)
Lumbar, Ectasia	2 (40%)
Lumbar, Hyperplasia, Plasma Cell	2 (40%)
Mediastinal, Hemorrhage	1 (20%)
Mediastinal, Hyperplasia, Plasma Cell	1 (20%)
Lymph Node, Mandibular	(49)
Ectasia	2 (4%)
Hyperplasia, Lymphoid	2 (4%)
Hyperplasia, Plasma Cell	30 (61%)
Lymph Node, Mesenteric	(49)
Hyperplasia, Histiocytic	1 (2%)
Spleen	(49)
Hematopoietic Cell Proliferation	42 (86%)
Hyperplasia, Lymphoid	1 (2%)
Pigmentation	42 (86%)
Lymphoid Follicle, Atrophy	1 (2%)
Red Pulp, Atrophy	1 (2%)
Thymus	(49)
Atrophy	45 (92%)
INTEGUMENTARY SYSTEM	
Mammary Gland	(50)
Cyst	4 (8%)
Hyperplasia	19 (38%)
Skin	(50)
Ulcer	1 (2%)

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

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
MUSCULOSKELETAL SYSTEM	
None	
NERVOUS SYSTEM	
Brain	(50)
Hemorrhage	1 (2%)
Inflammation, Suppurative	1 (2%)
RESPIRATORY SYSTEM	
Lung	(50)
Infiltration Cellular, Histiocyte	41 (82%)
Inflammation, Suppurative	1 (2%)
Metaplasia, Squamous	3 (6%)
Alveolar Epithelium, Metaplasia, Bronchiolar	31 (62%)
Serosa, Inflammation, Suppurative	1 (2%)
Nose	(50)
Inflammation	1 (2%)
Goblet Cell, Respiratory Epithelium, Hyperplasia	1 (2%)
Nasolacrimal Duct, Inflammation	1 (2%)
Olfactory Epithelium, Degeneration	1 (2%)
Olfactory Epithelium, Inflammation	1 (2%)
Olfactory Epithelium, Glands, Hyperplasia	1 (2%)
Respiratory Epithelium, Cyst	1 (2%)
Respiratory Epithelium, Inflammation, Suppurative	1 (2%)
SPECIAL SENSES SYSTEM	
Eye	(50)
Retinal Detachment	1 (2%)
Bilateral, Cataract	1 (2%)
Retina, Atrophy	6 (12%)
Retina, Degeneration	1 (2%)
Harderian Gland	(50)
Hemorrhage	1 (2%)
Inflammation	9 (18%)

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

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
URINARY SYSTEM	
Kidney	(50)
Accumulation, Hyaline Droplet	2 (4%)
Casts Protein	1 (2%)
Mineralization	42 (84%)
Nephropathy	41 (82%)
Papilla, Transitional Epithelium, Hyperplasia	1 (2%)
Pelvis, Dilatation	1 (2%)
Transitional Epithelium, Hyperplasia	5 (10%)
Urinary Bladder	(50)
Inflammation	2 (4%)

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

END OF REPORT

FINAL#2/RATS

Facility: Battelle Columbus Laboratory

Chemical CAS #: 1746-01-6

Lock Date: 06/28/01

Cage Range: All

Reasons For Removal: 25022 Accidently Killed
25019 Moribund Sacrifice
25021 Terminal Sacrifice
25018 Dosing Accident
25020 Natural Death

Removal Date Range: All

Treatment Groups: Include All

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

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
DISPOSITION SUMMARY						
Animals Initially in Study	98	98	98	98	98	98
Early Deaths						
Moribund Sacrifice	19	27	15	19	17	17
Natural Death	9	6	10	15	14	15
Dosing Accident			5			
Survivors						
Terminal Sacrifice	25	21	23	19	22	21
Animals Examined Microscopically	53	54	53	53	53	53
ALIMENTARY SYSTEM						
Intestine Large, Rectum	(52)	(54)	(53)	(52)	(53)	(53)
Carcinoma		1 (2%)				
Intestine Small, Jejunum	(51)	(54)	(53)	(53)	(53)	(52)
Leiomyoma					1 (2%)	
Liver	(53)	(54)	(53)	(53)	(53)	(53)
Carcinoma, Metastatic, Pancreas						2 (4%)
Carcinoma, Metastatic, Uterus					2 (4%)	
Cholangiocarcinoma				1 (2%)	3 (6%)	8 (15%)
Cholangiocarcinoma, Multiple					1 (2%)	17 (32%)
Hepatocellular Adenoma						5 (9%)
Hepatocellular Adenoma, Multiple						1 (2%)
Hepatocholangioma						1 (2%)
Mesentery	(2)	(2)		(1)	(6)	(8)
Carcinoma, Metastatic, Uterus					1 (17%)	
Schwannoma Malignant	1 (50%)					
Oral Mucosa	(2)	(9)	(16)	(16)	(22)	(29)
Gingival, Squamous Cell Carcinoma	1 (50%)	2 (22%)	1 (6%)		4 (18%)	10 (34%)
Pancreas	(51)	(54)	(52)	(53)	(52)	(51)
Carcinoma, Metastatic, Uterus					1 (2%)	
Acinus, Adenoma						1 (2%)
Acinus, Carcinoma						2 (4%)
Stomach, Forestomach	(53)	(54)	(53)	(53)	(53)	(53)
Squamous Cell Carcinoma	1 (2%)				1 (2%)	
Squamous Cell Papilloma					1 (2%)	1 (2%)
Stomach, Glandular	(53)	(54)	(53)	(53)	(53)	(53)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
CARDIOVASCULAR SYSTEM						
Heart	(53)	(54)	(53)	(52)	(53)	(52)
Schwannoma Malignant		1 (2%)				
ENDOCRINE SYSTEM						
Adrenal Cortex	(53)	(54)	(53)	(53)	(53)	(53)
Adenoma	1 (2%)		2 (4%)	2 (4%)	1 (2%)	1 (2%)
Carcinoma				1 (2%)		
Pheochromocytoma Benign						1 (2%)
Capsule, Sarcoma, Metastatic, Skeletal Muscle			1 (2%)			
Adrenal Medulla	(53)	(54)	(53)	(53)	(53)	(53)
Pheochromocytoma Malignant						1 (2%)
Pheochromocytoma Benign	3 (6%)	2 (4%)	2 (4%)	3 (6%)	3 (6%)	3 (6%)
Islets, Pancreatic	(51)	(54)	(53)	(53)	(52)	(52)
Adenoma	1 (2%)		2 (4%)			
Carcinoma	1 (2%)					
Parathyroid Gland	(46)	(47)	(47)	(44)	(45)	(45)
Adenoma				1 (2%)		
Pituitary Gland	(53)	(54)	(52)	(53)	(53)	(52)
Adenoma	4 (8%)					1 (2%)
Meningioma Malignant, Metastatic, Brain				1 (2%)		
Pars Distalis, Adenoma	18 (34%)	20 (37%)	26 (50%)	15 (28%)	20 (38%)	10 (19%)
Pars Distalis, Adenoma, Multiple	3 (6%)					
Pars Intermedia, Adenoma	2 (4%)					
Thyroid Gland	(52)	(54)	(53)	(51)	(53)	(52)
Bilateral, C-Cell, Adenoma	3 (6%)	3 (6%)	2 (4%)	2 (4%)	1 (2%)	3 (6%)
C-Cell, Adenoma	17 (33%)	12 (22%)	15 (28%)	14 (27%)	12 (23%)	8 (15%)
C-Cell, Carcinoma	1 (2%)	1 (2%)			2 (4%)	
Follicular Cell, Adenoma	1 (2%)					
Follicular Cell, Carcinoma					1 (2%)	
GENERAL BODY SYSTEM						
None						

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
GENITAL SYSTEM						
Clitoral Gland	(50)	(52)	(53)	(52)	(51)	(53)
Ovary	(51)	(53)	(53)	(53)	(53)	(53)
Granulosa Cell Tumor Malignant					1 (2%)	
Thecoma Benign					1 (2%)	
Periovarian Tissue, Schwannoma Malignant, Metastatic, Uterus	1 (2%)					
Uterus	(52)	(53)	(53)	(53)	(53)	(53)
Adenoma			1 (2%)			
Carcinoma		1 (2%)			2 (4%)	1 (2%)
Carcinoma, Multiple				1 (2%)		
Hemangiosarcoma					1 (2%)	
Leiomyoma	1 (2%)					
Polyp Stromal	9 (17%)	7 (13%)	4 (8%)	8 (15%)	9 (17%)	7 (13%)
Polyp Stromal, Multiple	2 (4%)			3 (6%)	1 (2%)	1 (2%)
Squamous Cell Carcinoma					4 (8%)	
Squamous Cell Carcinoma, Multiple					1 (2%)	
Squamous Cell Papilloma	1 (2%)		1 (2%)			
Cervix, Carcinoma		1 (2%)				
Cervix, Schwannoma Malignant	1 (2%)					
Vagina		(1)	(1)	(3)	(3)	(1)
Schwannoma Malignant					1 (33%)	1 (100%)
Schwannoma Malignant, Metastatic, Skin				1 (33%)		
Squamous Cell Carcinoma					1 (33%)	
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(54)	(53)	(53)	(53)	(53)
Lymph Node	(2)	(6)	(3)	(5)	(6)	(9)
Deep Cervical, Carcinoma, Metastatic, Thyroid Gland	1 (50%)					
Lumbar, Carcinoma, Metastatic, Uterus					1 (17%)	
Lymph Node, Mandibular	(51)	(54)	(52)	(50)	(51)	(52)
Lymph Node, Mesenteric	(52)	(53)	(53)	(53)	(53)	(51)
Spleen	(51)	(54)	(53)	(53)	(52)	(52)
Hemangiosarcoma					1 (2%)	
Schwannoma Malignant, Metastatic, Uterus	1 (2%)					
Thymus	(51)	(52)	(52)	(49)	(46)	(42)
Carcinoma, Metastatic, Lung		1 (2%)				
Histiocytic Sarcoma, Metastatic, Lung			1 (2%)			

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
INTEGUMENTARY SYSTEM						
Mammary Gland	(53)	(54)	(53)	(53)	(53)	(53)
Adenoma	2 (4%)		1 (2%)			1 (2%)
Carcinoma	3 (6%)	7 (13%)	4 (8%)	2 (4%)	2 (4%)	
Carcinoma, Multiple	1 (2%)	1 (2%)				
Fibroadenoma	21 (40%)	26 (48%)	17 (32%)	17 (32%)	24 (45%)	20 (38%)
Fibroadenoma, Multiple	12 (23%)	14 (26%)	17 (32%)	12 (23%)	12 (23%)	4 (8%)
Skin	(53)	(54)	(53)	(53)	(53)	(53)
Basal Cell Carcinoma	1 (2%)		1 (2%)			
Fibroma	1 (2%)		2 (4%)			1 (2%)
Fibrosarcoma				1 (2%)		
Keratoacanthoma				1 (2%)		
Lipoma		1 (2%)				
Myxosarcoma			1 (2%)			
Schwannoma Malignant	1 (2%)			2 (4%)		1 (2%)
MUSCULOSKELETAL SYSTEM						
Bone	(53)	(54)	(53)	(53)	(53)	(53)
Cranium, Schwannoma Malignant, Metastatic, Skin				1 (2%)		
Periosteum, Fibrosarcoma				1 (2%)		
Skeletal Muscle			(1)	(2)		
Fibrous Histiocytoma				1 (50%)		
Sarcoma			1 (100%)			
NERVOUS SYSTEM						
Brain	(53)	(54)	(53)	(53)	(53)	(53)
Glioma Malignant			1 (2%)			
Granular Cell Tumor Malignant			1 (2%)			
RESPIRATORY SYSTEM						
Lung	(53)	(54)	(53)	(52)	(53)	(52)
Alveolar/Bronchiolar Adenoma, Multiple					1 (2%)	
Alveolar/Bronchiolar Carcinoma		1 (2%)				
Carcinoma, Metastatic, Mammary Gland		1 (2%)				
Carcinoma, Metastatic, Pancreas						1 (2%)
Carcinoma, Metastatic, Thyroid Gland	1 (2%)					

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
RESPIRATORY SYSTEM - cont						
Cystic Keratinizing Epithelioma						7 (13%)
Cystic Keratinizing Epithelioma, Multiple						2 (4%)
Nephroblastoma, Metastatic, Kidney		1 (2%)				
Sarcoma, Metastatic, Skeletal Muscle			1 (2%)			
Mediastinum, Sarcoma			1 (2%)			1 (2%)
Nose	(53)	(54)	(53)	(53)	(53)	(53)
Squamous Cell Carcinoma, Metastatic, Oral Mucosa						1 (2%)
SPECIAL SENSES SYSTEM						
Ear	(2)		(2)			(1)
Pinna, Neural Crest Tumor	1 (50%)					
Harderian Gland	(53)	(54)	(53)	(52)	(53)	(53)
Squamous Cell Carcinoma, Metastatic, Oral Mucosa						3 (6%)
Zymbal's Gland	(1)					
Carcinoma	1 (100%)					
URINARY SYSTEM						
Kidney	(53)	(54)	(53)	(53)	(53)	(53)
Nephroblastoma		2 (4%)	1 (2%)			
Schwannoma Malignant, Metastatic, Uterus	1 (2%)					
Stromal Nephroma				1 (2%)		
Urinary Bladder	(52)	(53)	(53)	(52)	(53)	(53)
Polyp		1 (2%)				
Schwannoma Malignant, Metastatic, Uterus	1 (2%)					
Squamous Cell Carcinoma, Metastatic, Uterus					1 (2%)	
Transitional Epithelium, Carcinoma					1 (2%)	
SYSTEMIC LESIONS						
Multiple Organs	*(53)	*(54)	*(53)	*(53)	*(53)	*(53)
Leukemia Granulocytic			1 (2%)			
Lymphoma Malignant		1 (2%)	1 (2%)		1 (2%)	2 (4%)

* Number of animals with any tissue examined microscopically

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
TUMOR SUMMARY						
Total Animals with Primary Neoplasms (b)	47	54	48	44	50	49
Total Primary Neoplasms	116	105	106	89	115	123
Total Animals with Benign Neoplasms	45	49	45	40	46	39
Total Benign Neoplasms	102	86	92	78	87	79
Total Animals with Malignant Neoplasms	13	19	13	11	24	34
Total Malignant Neoplasms	13	19	14	11	28	44
Total Animals with Metastatic Neoplasms	2	3	2	2	3	6
Total Metastatic Neoplasm	6	3	3	3	6	7
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

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
DISPOSITION SUMMARY	
Animals Initially in Study	50
Early Deaths	
Moribund Sacrifice	16
Natural Death	13
Survivors	
Terminal Sacrifice	21
Animals Examined Microscopically	50
ALIMENTARY SYSTEM	
Intestine Large, Rectum	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)
Intestine Small, Jejunum	(50)
Schwannoma Malignant, Metastatic, Heart	1 (2%)
Liver	(50)
Cholangiocarcinoma	1 (2%)
Cholangiocarcinoma, Multiple	1 (2%)
Cholangioma	1 (2%)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)
Hepatocellular Adenoma	2 (4%)
Schwannoma Malignant, Metastatic, Heart	1 (2%)
Oral Mucosa	(11)
Gingival, Squamous Cell Carcinoma	5 (45%)
Pancreas	(49)
Acinus, Carcinoma	1 (2%)
Tongue	(1)
Squamous Cell Carcinoma	1 (100%)
CARDIOVASCULAR SYSTEM	
Blood Vessel	(49)
Aorta, Fibrous Histiocytoma, Metastatic, Skin	1 (2%)
Heart	(50)
Carcinoma, Metastatic, Mammary Gland	1 (2%)
Schwannoma Malignant	3 (6%)

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
ENDOCRINE SYSTEM	
Adrenal Cortex	(50)
Capsule, Schwannoma Malignant, Metastatic, Heart	1 (2%)
Adrenal Medulla	(50)
Pheochromocytoma Complex	1 (2%)
Pheochromocytoma Benign	1 (2%)
Pituitary Gland	(50)
Pars Distalis, Adenoma	19 (38%)
Thyroid Gland	(49)
Bilateral, C-Cell, Adenoma	2 (4%)
C-Cell, Adenoma	11 (22%)
C-Cell, Carcinoma	1 (2%)
GENERAL BODY SYSTEM	
None	
GENITAL SYSTEM	
Ovary	(49)
Carcinoma, Metastatic, Uterus	1 (2%)
Uterus	(50)
Carcinoma	2 (4%)
Polyp Stromal	3 (6%)
Polyp Stromal, Multiple	1 (2%)
Squamous Cell Carcinoma	2 (4%)
HEMATOPOIETIC SYSTEM	
Bone Marrow	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)
Lymph Node, Mesenteric	(49)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)
Spleen	(49)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)
Hemangiosarcoma	1 (2%)
Schwannoma Malignant, Metastatic, Heart	1 (2%)
Thymus	(49)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
HEMATOPOIETIC SYSTEM - cont	
Thymoma Malignant	1 (2%)
INTEGUMENTARY SYSTEM	
Mammary Gland	(50)
Adenolipoma	1 (2%)
Carcinoma	1 (2%)
Fibroadenoma	19 (38%)
Fibroadenoma, Multiple	13 (26%)
Skin	(50)
Fibroma	1 (2%)
Fibrous Histiocytoma	1 (2%)
Liposarcoma	1 (2%)
MUSCULOSKELETAL SYSTEM	
Bone	(50)
Squamous Cell Carcinoma, Metastatic, Tongue	1 (2%)
Skeletal Muscle	(1)
Fibrous Histiocytoma, Metastatic, Skin	1 (100%)
NERVOUS SYSTEM	
None	
RESPIRATORY SYSTEM	
Lung	(50)
Carcinoma, Metastatic, Mammary Gland	1 (2%)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)
Schwannoma Malignant, Metastatic, Heart	1 (2%)
SPECIAL SENSES SYSTEM	
None	

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
URINARY SYSTEM	
Kidney	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)
SYSTEMIC LESIONS	
Multiple Organs	*(50)
Adenolipoma	1 (2%)
Lymphoma Malignant	1 (2%)

* Number of animals with any tissue examined microscopically

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
TUMOR SUMMARY	
Total Animals with Primary Neoplasms (b)	46
Total Primary Neoplasms	98
Total Animals with Benign Neoplasms	41
Total Benign Neoplasms	74
Total Animals with Malignant Neoplasms	19
Total Malignant Neoplasms	24
Total Animals with Metastatic Neoplasms	5
Total Metastatic Neoplasm	19
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#2/RATS CTRL VS STOP GRP

REASONS FOR REMOVAL:
25022 Accidently Killed
25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:
INCLUDE 001 0 NG/KG
INCLUDE 007 100 NG/ KG/STOP

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 03
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD
Rats(SPRAGUE-DAWLEY)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/21/03
TIME: 15:36:46

NTP C#: 96007G
CAS: 1746-01-6

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
Liver
Pancreas
Pituitary Gland
Spleen
Thymus
Thyroid Gland

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 03
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/21/03
TIME: 15:36:46

NTP C#: 96007G
CAS: 1746-01-6

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TOXIC EQUIVALENCY FACTOR EVALUATION

Female Rats

Organ	Morphology
Adrenal Medulla	Pheochromocytoma Benign
	Pheochromocytoma: Benign, Complex, Malignant, NOS
Heart	Schwannoma Malignant
Islets, Pancreatic	Carcinoma or Adenoma
Liver	Cholangiocarcinoma
	Hepatocellular Adenoma
Mammary Gland	Adenoma
	Carcinoma
	Carcinoma or Adenoma
	Fibroadenoma
	Fibroma, Fibroadenoma or Adenoma
	Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)	Squamous Cell Carcinoma
	Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma
Oral Mucosa	Squamous Cell Carcinoma
Pituitary Gland: Pars Distalis or Unspecified Site	Adenoma
Pituitary Gland: Pars Intermedia	Adenoma
Skin	Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma
Thyroid Gland: C-Cell	Adenoma
	Carcinoma or Adenoma
Uterus	Carcinoma
	Polyp Stromal
	Squamous Cell Carcinoma
All Organs	Benign Tumors
	Malignant Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Adrenal Medulla		
Pheochromocytoma Benign		
TUMOR RATES		
OVERALL (a)	3/53 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/39.55	1/38.27
POLY-3 PERCENT (g)	7.6%	2.6%
TERMINAL (d)	3/25 (12%)	0/21 (0%)
FIRST INCIDENCE	731 (T)	702
STATISTICAL TESTS		
LIFE TABLE		P=0.350N
POLY 3		P=0.319N
POLY 1.5		P=0.320N
POLY 6		P=0.321N
LOGISTIC REGRESSION		P=0.325N
COCH-ARM / FISHERS		P=0.331N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Adrenal Medulla		
Pheochromocytoma: Benign, Complex, Malignant, NOS		
TUMOR RATES		
OVERALL (a)	3/53 (6%)	2/50 (4%)
POLY-3 RATE (b)	3/39.55	2/38.27
POLY-3 PERCENT (g)	7.6%	5.2%
TERMINAL (d)	3/25 (12%)	1/21 (5%)
FIRST INCIDENCE	731 (T)	702
STATISTICAL TESTS		
LIFE TABLE		P=0.560N
POLY 3		P=0.518N
POLY 1.5		P=0.519N
POLY 6		P=0.522N
LOGISTIC REGRESSION		P=0.528N
COCH-ARM / FISHERS		P=0.528N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Heart		
Schwannoma Malignant		
TUMOR RATES		
OVERALL (a)	0/53 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/39.55	3/38.98
POLY-3 PERCENT (g)	0.0%	7.7%
TERMINAL (d)	0/25 (0%)	1/21 (5%)
FIRST INCIDENCE	---	484
STATISTICAL TESTS		
LIFE TABLE		P=0.115
POLY 3		P=0.116
POLY 1.5		P=0.115
POLY 6		P=0.115
LOGISTIC REGRESSION		P=0.110
COCH-ARM / FISHERS		P=0.111
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Islets, Pancreatic		
Carcinoma or Adenoma		
TUMOR RATES		
OVERALL (a)	2/51 (4%)	0/49 (0%)
POLY-3 RATE (b)	2/39.17	0/37.76
POLY-3 PERCENT (g)	5.1%	0.0%
TERMINAL (d)	1/25 (4%)	0/21 (0%)
FIRST INCIDENCE	645	---
STATISTICAL TESTS		
LIFE TABLE		P=0.275N
POLY 3		P=0.249N
POLY 1.5		P=0.247N
POLY 6		P=0.255N
LOGISTIC REGRESSION		P=0.244N
COCH-ARM / FISHERS		P=0.258N
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Liver		
Cholangiocarcinoma		
TUMOR RATES		
OVERALL (a)	0/53 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/39.55	2/38.16
POLY-3 PERCENT (g)	0.0%	5.2%
TERMINAL (d)	0/25 (0%)	1/21 (5%)
FIRST INCIDENCE	---	729
STATISTICAL TESTS		
LIFE TABLE		P=0.207
POLY 3		P=0.232
POLY 1.5		P=0.233
POLY 6		P=0.231
LOGISTIC REGRESSION		P=0.221
COCH-ARM / FISHERS		P=0.233
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Liver		
Hepatocellular Adenoma		
TUMOR RATES		
OVERALL (a)	0/53 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/39.55	2/38.29
POLY-3 PERCENT (g)	0.0%	5.2%
TERMINAL (d)	0/25 (0%)	0/21 (0%)
FIRST INCIDENCE	---	702
STATISTICAL TESTS		
LIFE TABLE		P=0.239
POLY 3		P=0.233
POLY 1.5		P=0.233
POLY 6		P=0.232
LOGISTIC REGRESSION		P=0.226
COCH-ARM / FISHERS		P=0.233
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

	Females	
Dose	0 NG/KG	100 NG/ KG/STOP
Mammary Gland Adenoma		
TUMOR RATES	#	#
OVERALL (a)	2/53 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/39.90	0/38.16
POLY-3 PERCENT (g)	5.0%	0.0%
TERMINAL (d)	1/25 (4%)	0/21 (0%)
FIRST INCIDENCE	631	---
STATISTICAL TESTS		
LIFE TABLE		P=0.271N
POLY 3		P=0.252N
POLY 1.5		P=0.250N
POLY 6		P=0.257N
LOGISTIC REGRESSION		P=0.246N
COCH-ARM / FISHERS		P=0.262N
ORDER RESTRICTED		(e)

	Females	
Dose	0 NG/KG	100 NG/ KG/STOP
Mammary Gland Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	4/53 (8%)	1/50 (2%)
POLY-3 RATE (b)	4/40.42	1/38.76
POLY-3 PERCENT (g)	9.9%	2.6%
TERMINAL (d)	2/25 (8%)	0/21 (0%)
FIRST INCIDENCE	469	537
STATISTICAL TESTS		
LIFE TABLE		P=0.208N
POLY 3		P=0.192N
POLY 1.5		P=0.193N
POLY 6		P=0.196N
LOGISTIC REGRESSION		P=0.200N
COCH-ARM / FISHERS		P=0.200N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Mammary Gland Carcinoma or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	6/53 (11%)	1/50 (2%)
POLY-3 RATE (b)	6/40.77	1/38.76
POLY-3 PERCENT (g)	14.7%	2.6%
TERMINAL (d)	3/25 (12%)	0/21 (0%)
FIRST INCIDENCE	469	537
STATISTICAL TESTS		
LIFE TABLE		P=0.080N
POLY 3		P=0.064N
POLY 1.5		P=0.063N
POLY 6		P=0.066N
LOGISTIC REGRESSION		P=0.068N
COCH-ARM / FISHERS		P=0.066N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Mammary Gland Fibroadenoma		
TUMOR RATES	#	#
OVERALL (a)	33/53 (62%)	32/50 (64%)
POLY-3 RATE (b)	33/46.50	32/44.58
POLY-3 PERCENT (g)	71.0%	71.8%
TERMINAL (d)	16/25 (64%)	13/21 (62%)
FIRST INCIDENCE	185	345
STATISTICAL TESTS		
LIFE TABLE		P=0.410
POLY 3		P=0.562
POLY 1.5		P=0.551
POLY 6		P=0.565
LOGISTIC REGRESSION		P=0.544
COCH-ARM / FISHERS		P=0.509
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

	Females	
Dose	0 NG/KG	100 NG/ KG/STOP
Mammary Gland Fibroma, Fibroadenoma or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	35/53 (66%)	32/50 (64%)
POLY-3 RATE (b)	35/46.86	32/44.58
POLY-3 PERCENT (g)	74.7%	71.8%
TERMINAL (d)	17/25 (68%)	13/21 (62%)
FIRST INCIDENCE	185	345
STATISTICAL TESTS		
LIFE TABLE		P=0.518
POLY 3		P=0.470N
POLY 1.5		P=0.469N
POLY 6		P=0.489N
LOGISTIC REGRESSION		P=0.457N
COCH-ARM / FISHERS		P=0.496N
ORDER RESTRICTED		(e)

	Females	
Dose	0 NG/KG	100 NG/ KG/STOP
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma		
TUMOR RATES	#	#
OVERALL (a)	35/53 (66%)	33/50 (66%)
POLY-3 RATE (b)	35/46.86	33/45.18
POLY-3 PERCENT (g)	74.7%	73.0%
TERMINAL (d)	17/25 (68%)	13/21 (62%)
FIRST INCIDENCE	185	345
STATISTICAL TESTS		
LIFE TABLE		P=0.462
POLY 3		P=0.525N
POLY 1.5		P=0.539N
POLY 6		P=0.525N
LOGISTIC REGRESSION		P=0.547N
COCH-ARM / FISHERS		P=0.581N
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	1/53 (2%)	5/50 (10%)
POLY-3 RATE (b)	1/40.42	5/40.28
POLY-3 PERCENT (g)	2.5%	12.4%
TERMINAL (d)	0/25 (0%)	0/21 (0%)
FIRST INCIDENCE	366	520
STATISTICAL TESTS		
LIFE TABLE		P=0.109
POLY 3		P=0.099
POLY 1.5		P=0.097
POLY 6		P=0.102
LOGISTIC REGRESSION		P=0.070
COCH-ARM / FISHERS		P=0.090
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma		
TUMOR RATES	#	#
OVERALL (a)	1/53 (2%)	5/50 (10%)
POLY-3 RATE (b)	1/40.42	5/40.28
POLY-3 PERCENT (g)	2.5%	12.4%
TERMINAL (d)	0/25 (0%)	0/21 (0%)
FIRST INCIDENCE	366	520
STATISTICAL TESTS		
LIFE TABLE		P=0.109
POLY 3		P=0.099
POLY 1.5		P=0.097
POLY 6		P=0.102
LOGISTIC REGRESSION		P=0.070
COCH-ARM / FISHERS		P=0.090
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Oral Mucosa		
Squamous Cell Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	1/53 (2%)	5/50 (10%)
POLY-3 RATE (b)	1/40.42	5/40.28
POLY-3 PERCENT (g)	2.5%	12.4%
TERMINAL (d)	0/25 (0%)	0/21 (0%)
FIRST INCIDENCE	366	520
STATISTICAL TESTS		
LIFE TABLE		P=0.109
POLY 3		P=0.099
POLY 1.5		P=0.097
POLY 6		P=0.102
LOGISTIC REGRESSION		P=0.070
COCH-ARM / FISHERS		P=0.090
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Pituitary Gland: Pars Distalis or Unspecified Site		
Adenoma		
TUMOR RATES		
OVERALL (a)	25/53 (47%)	19/50 (38%)
POLY-3 RATE (b)	25/42.82	19/39.99
POLY-3 PERCENT (g)	58.4%	47.5%
TERMINAL (d)	15/25 (60%)	9/21 (43%)
FIRST INCIDENCE	474	584
STATISTICAL TESTS		
LIFE TABLE		P=0.339N
POLY 3		P=0.213N
POLY 1.5		P=0.205N
POLY 6		P=0.241N
LOGISTIC REGRESSION		P=0.183N
COCH-ARM / FISHERS		P=0.229N
ORDER RESTRICTED		(e)

	Females	
Dose	0 NG/KG	100 NG/ KG/STOP
Pituitary Gland: Pars Intermedia		
Adenoma		
TUMOR RATES		
OVERALL (a)	2/53 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/39.60	0/38.16
POLY-3 PERCENT (g)	5.1%	0.0%
TERMINAL (d)	1/25 (4%)	0/21 (0%)
FIRST INCIDENCE	717	---
STATISTICAL TESTS		
LIFE TABLE		P=0.263N
POLY 3		P=0.249N
POLY 1.5		P=0.249N
POLY 6		P=0.252N
LOGISTIC REGRESSION		P=0.250N
COCH-ARM / FISHERS		P=0.262N
ORDER RESTRICTED		(e)

	Females	
Dose	0 NG/KG	100 NG/ KG/STOP
Skin		
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma		
TUMOR RATES	#	#
OVERALL (a)	1/53 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/40.13	2/39.00
POLY-3 PERCENT (g)	2.5%	5.1%
TERMINAL (d)	0/25 (0%)	1/21 (5%)
FIRST INCIDENCE	548	394
STATISTICAL TESTS		
LIFE TABLE		P=0.483
POLY 3		P=0.493
POLY 1.5		P=0.493
POLY 6		P=0.491
LOGISTIC REGRESSION		P=0.447
COCH-ARM / FISHERS		P=0.478
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Thyroid Gland: C-Cell Adenoma		
TUMOR RATES		
OVERALL (a)	20/52 (38%)	13/49 (27%)
POLY-3 RATE (b)	20/42.85	13/38.54
POLY-3 PERCENT (g)	46.7%	33.7%
TERMINAL (d)	10/25 (40%)	7/21 (33%)
FIRST INCIDENCE	474	584
STATISTICAL TESTS		
LIFE TABLE		P=0.211N
POLY 3		P=0.166N
POLY 1.5		P=0.145N
POLY 6		P=0.208N
LOGISTIC REGRESSION		P=0.121N
COCH-ARM / FISHERS		P=0.143N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Thyroid Gland: C-Cell Carcinoma or Adenoma		
TUMOR RATES		
OVERALL (a)	21/52 (40%)	14/49 (29%)
POLY-3 RATE (b)	21/42.85	14/38.54
POLY-3 PERCENT (g)	49.0%	36.3%
TERMINAL (d)	11/25 (44%)	8/21 (38%)
FIRST INCIDENCE	474	584
STATISTICAL TESTS		
LIFE TABLE		P=0.223N
POLY 3		P=0.173N
POLY 1.5		P=0.151N
POLY 6		P=0.219N
LOGISTIC REGRESSION		P=0.124N
COCH-ARM / FISHERS		P=0.150N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Uterus Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	0/53 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/39.55	2/38.16
POLY-3 PERCENT (g)	0.0%	5.2%
TERMINAL (d)	0/25 (0%)	2/21 (10%)
FIRST INCIDENCE	---	731 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.200
POLY 3		P=0.232
POLY 1.5		P=0.233
POLY 6		P=0.231
LOGISTIC REGRESSION		P=0.200
COCH-ARM / FISHERS		P=0.233
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Uterus Polyp Stromal		
TUMOR RATES	#	#
OVERALL (a)	11/53 (21%)	4/50 (8%)
POLY-3 RATE (b)	11/40.11	4/38.16
POLY-3 PERCENT (g)	27.4%	10.5%
TERMINAL (d)	8/25 (32%)	3/21 (14%)
FIRST INCIDENCE	645	729
STATISTICAL TESTS		
LIFE TABLE		P=0.083N
POLY 3		P=0.050N
POLY 1.5		P=0.051N
POLY 6		P=0.053N
LOGISTIC REGRESSION		P=0.051N
COCH-ARM / FISHERS		P=0.059N
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
Uterus		
Squamous Cell Carcinoma		
TUMOR RATES	#	#
OVERALL (a)	0/53 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/39.55	2/38.16
POLY-3 PERCENT (g)	0.0%	5.2%
TERMINAL (d)	0/25 (0%)	2/21 (10%)
FIRST INCIDENCE	---	731 (T)
STATISTICAL TESTS		
LIFE TABLE		P=0.200
POLY 3		P=0.232
POLY 1.5		P=0.233
POLY 6		P=0.231
LOGISTIC REGRESSION		P=0.200
COCH-ARM / FISHERS		P=0.233
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
All Organs		
Benign Tumors		
TUMOR RATES	#	#
OVERALL (a)	45/53 (85%)	41/50 (82%)
POLY-3 RATE (b)	45/48.82	41/45.87
POLY-3 PERCENT (g)	92.2%	89.4%
TERMINAL (d)	23/25 (92%)	18/21 (86%)
FIRST INCIDENCE	185	345
STATISTICAL TESTS		
LIFE TABLE		P=0.518
POLY 3		P=0.455N
POLY 1.5		P=0.434N
POLY 6		P=0.490N
LOGISTIC REGRESSION		P=0.347N
COCH-ARM / FISHERS		P=0.447N
ORDER RESTRICTED		(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
All Organs Malignant Tumors		
TUMOR RATES	#	#
OVERALL (a)	13/53 (25%)	19/50 (38%)
POLY-3 RATE (b)	13/43.94	19/42.85
POLY-3 PERCENT (g)	29.6%	44.3%
TERMINAL (d)	4/25 (16%)	9/21 (43%)
FIRST INCIDENCE	169	345
STATISTICAL TESTS		
LIFE TABLE		P=0.111
POLY 3		P=0.110
POLY 1.5		P=0.110
POLY 6		P=0.102
LOGISTIC REGRESSION		P=0.094
COCH-ARM / FISHERS		P=0.103
ORDER RESTRICTED		(e)

Dose	Females 0 NG/KG	Females 100 NG/KG/STOP
All Organs Malignant and Benign Tumors		
TUMOR RATES	#	#
OVERALL (a)	47/53 (89%)	46/50 (92%)
POLY-3 RATE (b)	47/50.68	46/48.66
POLY-3 PERCENT (g)	92.7%	94.5%
TERMINAL (d)	23/25 (92%)	19/21 (91%)
FIRST INCIDENCE	169	345
STATISTICAL TESTS		
LIFE TABLE		P=0.352
POLY 3		P=0.522
POLY 1.5		P=0.451
POLY 6		P=0.609
LOGISTIC REGRESSION		P=0.441
COCH-ARM / FISHERS		P=0.408
ORDER RESTRICTED		(e)

(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).

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

FINAL#2/RATS CTRL VS STREATED GRPS

REASONS FOR REMOVAL:
25022 Accidently Killed
25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:
INCLUDE 001 0 NG/KG
INCLUDE 002 3 NG/KG
INCLUDE 003 10 NG/KG
INCLUDE 004 22 NG/KG
INCLUDE 005 46 NG/KG
INCLUDE 006 100 NG/KG

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

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
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Ovary
Pancreas
Parathyroid Gland
Pituitary Gland
Spleen
Thyroid Gland
Urinary Bladder

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 03
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/21/03
TIME: 15:40:18

NTP C#: 96007G
CAS: 1746-01-6

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TOXIC EQUIVALENCY FACTOR EVALUATION

Female Rats

Organ	Morphology
Liver	Cholangiocarcinoma
	Hepatocellular Adenoma
Lung	Cystic Keratinizing Epithelioma
Mammary Gland	Carcinoma
	Carcinoma or Adenoma
	Fibroadenoma
	Fibroma, Fibroadenoma or Adenoma
	Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)	Squamous Cell Carcinoma
	Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma
Oral Mucosa	Squamous Cell Carcinoma
Pancreas	Carcinoma
	Carcinoma or Adenoma
Pituitary Gland: Pars Distalis or Unspecified Site	Adenoma
Pituitary Gland: Pars Intermedia	Adenoma
Thyroid Gland: C-Cell	Adenoma
	Carcinoma or Adenoma
Uterus	Polyp Stromal
	Squamous Cell Carcinoma
All Organs	Benign Tumors
	Malignant Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	0 NG/KG	3 NG/KG	10 NG/KG	Females 22 NG/KG	46 NG/KG	100 NG/KG
Adrenal Cortex Adenoma						
TUMOR RATES						
OVERALL (a)	1/53 (2%)	0/54 (0%)	2/53 (4%)	2/53 (4%)	1/53 (2%)	1/53 (2%)
POLY-3 RATE (b)	1/39.55	0/34.61	2/38.75	2/34.53	1/39.00	1/42.90
POLY-3 PERCENT (g)	2.5%	0.0%	5.2%	5.8%	2.6%	2.3%
TERMINAL (d)	1/25 (4%)	0/21 (0%)	2/23 (9%)	1/19 (5%)	1/22 (5%)	0/21 (0%)
FIRST INCIDENCE	731 (T)	---	731 (T)	626	731 (T)	648
STATISTICAL TESTS						
LIFE TABLE	P=0.609N	P=0.535N	P=0.471	P=0.403	P=0.734	P=0.744
POLY 3	P=0.549N	P=0.527N	P=0.493	P=0.453	P=0.758	P=0.743N
POLY 1.5	P=0.567N	P=0.514N	P=0.490	P=0.472	P=0.759	P=0.745N
POLY 6	P=0.542N	P=0.539N	P=0.494	P=0.430	P=0.755	P=0.747N
LOGISTIC REGRESSION	P=0.560N	(e)	P=0.471	P=0.433	P=0.734	P=0.749N
COCH-ARM / FISHERS	P=0.614N	P=0.495N	P=0.500	P=0.500	P=0.752N	P=0.752N
ORDER RESTRICTED	P=0.450	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	Females 22 NG/KG	46 NG/KG	100 NG/KG
Adrenal Medulla Pheochromocytoma Benign						
TUMOR RATES						
OVERALL (a)	3/53 (6%)	2/54 (4%)	2/53 (4%)	3/53 (6%)	3/53 (6%)	3/53 (6%)
POLY-3 RATE (b)	3/39.55	2/34.61	2/38.75	3/34.16	3/39.09	3/43.18
POLY-3 PERCENT (g)	7.6%	5.8%	5.2%	8.8%	7.7%	7.0%
TERMINAL (d)	3/25 (12%)	2/21 (10%)	2/23 (9%)	3/19 (16%)	2/22 (9%)	0/21 (0%)
FIRST INCIDENCE	731 (T)	731 (T)	731 (T)	731 (T)	708	642
STATISTICAL TESTS						
LIFE TABLE	P=0.414	P=0.581N	P=0.539N	P=0.532	P=0.604	P=0.606
POLY 3	P=0.542	P=0.561N	P=0.509N	P=0.594	P=0.658	P=0.622N
POLY 1.5	P=0.516	P=0.533N	P=0.512N	P=0.623	P=0.660	P=0.629N
POLY 6	P=0.550	P=0.590N	P=0.508N	P=0.557	P=0.653	P=0.628N
LOGISTIC REGRESSION	P=0.492	P=0.581N	P=0.539N	P=0.532	P=0.618	P=0.642N
COCH-ARM / FISHERS	P=0.436	P=0.491N	P=0.500N	P=0.661N	P=0.661N	P=0.661N
ORDER RESTRICTED	P=0.688	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Adrenal Medulla						
Pheochromocytoma: Benign, Complex, Malignant, NOS						
TUMOR RATES						
OVERALL (a)	3/53 (6%)	2/54 (4%)	2/53 (4%)	3/53 (6%)	3/53 (6%)	3/53 (6%)
POLY-3 RATE (b)	3/39.55	2/34.61	2/38.75	3/34.16	3/39.09	3/43.18
POLY-3 PERCENT (g)	7.6%	5.8%	5.2%	8.8%	7.7%	7.0%
TERMINAL (d)	3/25 (12%)	2/21 (10%)	2/23 (9%)	3/19 (16%)	2/22 (9%)	0/21 (0%)
FIRST INCIDENCE	731 (T)	731 (T)	731 (T)	731 (T)	708	642
STATISTICAL TESTS						
LIFE TABLE	P=0.414	P=0.581N	P=0.539N	P=0.532	P=0.604	P=0.606
POLY 3	P=0.542	P=0.561N	P=0.509N	P=0.594	P=0.658	P=0.622N
POLY 1.5	P=0.516	P=0.533N	P=0.512N	P=0.623	P=0.660	P=0.629N
POLY 6	P=0.550	P=0.590N	P=0.508N	P=0.557	P=0.653	P=0.628N
LOGISTIC REGRESSION	P=0.492	P=0.581N	P=0.539N	P=0.532	P=0.618	P=0.642N
COCH-ARM / FISHERS	P=0.436	P=0.491N	P=0.500N	P=0.661N	P=0.661N	P=0.661N
ORDER RESTRICTED	P=0.688	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Islets, Pancreatic						
Adenoma						
TUMOR RATES						
OVERALL (a)	1/51 (2%)	0/54 (0%)	2/53 (4%)	0/53 (0%)	0/52 (0%)	0/52 (0%)
POLY-3 RATE (b)	1/38.86	0/34.61	2/38.75	0/34.16	0/38.45	0/41.64
POLY-3 PERCENT (g)	2.6%	0.0%	5.2%	0.0%	0.0%	0.0%
TERMINAL (d)	1/25 (4%)	0/21 (0%)	2/23 (9%)	0/19 (0%)	0/22 (0%)	0/21 (0%)
FIRST INCIDENCE	731 (T)	---	731 (T)	---	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.248N	P=0.535N	P=0.471	P=0.555N	P=0.525N	P=0.535N
POLY 3	P=0.205N	P=0.523N	P=0.499	P=0.526N	P=0.502N	P=0.486N
POLY 1.5	P=0.218N	P=0.509N	P=0.499	P=0.512N	P=0.500N	P=0.486N
POLY 6	P=0.196N	P=0.537N	P=0.497	P=0.542N	P=0.506N	P=0.493N
LOGISTIC REGRESSION	P=0.248N	(e)	P=0.471	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.236N	P=0.486N	P=0.515	P=0.490N	P=0.495N	P=0.495N
ORDER RESTRICTED	P=0.245N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

	Females					
Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Islets, Pancreatic Carcinoma or Adenoma						
TUMOR RATES						
OVERALL (a)	2/51 (4%)	0/54 (0%)	2/53 (4%)	0/53 (0%)	0/52 (0%)	0/52 (0%)
POLY-3 RATE (b)	2/39.17	0/34.61	2/38.75	0/34.16	0/38.45	0/41.64
POLY-3 PERCENT (g)	5.1%	0.0%	5.2%	0.0%	0.0%	0.0%
TERMINAL (d)	1/25 (4%)	0/21 (0%)	2/23 (9%)	0/19 (0%)	0/22 (0%)	0/21 (0%)
FIRST INCIDENCE	645	---	731 (T)	---	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.149N	P=0.302N	P=0.662	P=0.318N	P=0.260N	P=0.265N
POLY 3	P=0.115N	P=0.265N	P=0.691	P=0.268N	P=0.241N	P=0.223N
POLY 1.5	P=0.126N	P=0.248N	P=0.692	P=0.252N	P=0.238N	P=0.223N
POLY 6	P=0.107N	P=0.285N	P=0.687	P=0.291N	P=0.246N	P=0.232N
LOGISTIC REGRESSION	P=0.133N	P=0.263N	P=0.693	P=0.267N	P=0.239N	P=0.224N
COCH-ARM / FISHERS	P=0.144N	P=0.234N	P=0.676N	P=0.238N	P=0.243N	P=0.243N
ORDER RESTRICTED	P=0.053N	(e)	(e)	(e)	(e)	(e)

	Females					
Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Kidney: Renal Tubule Nephroblastoma						
TUMOR RATES						
OVERALL (a)	0/53 (0%)	2/54 (4%)	1/53 (2%)	0/53 (0%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	0/39.55	2/36.54	1/39.71	0/34.16	0/39.00	0/42.60
POLY-3 PERCENT (g)	0.0%	5.5%	2.5%	0.0%	0.0%	0.0%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	0/22 (0%)	0/21 (0%)
FIRST INCIDENCE	---	200	240	---	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.212N	P=0.248	P=0.492	(e)	(e)	(e)
POLY 3	P=0.218N	P=0.219	P=0.501	(e)	(e)	(e)
POLY 1.5	P=0.215N	P=0.230	P=0.498	(e)	(e)	(e)
POLY 6	P=0.224N	P=0.208	P=0.502	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.374N	P=0.189	P=0.663	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.215N	P=0.252	P=0.500	(e)	(e)	(e)
ORDER RESTRICTED	P=0.243N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Liver						
Cholangiocarcinoma						
TUMOR RATES						
OVERALL (a)	0/53 (0%)	0/54 (0%)	0/53 (0%)	1/53 (2%)	4/53 (8%)	25/53 (47%)
POLY-3 RATE (b)	0/39.55	0/34.61	0/38.75	1/34.63	4/39.00	25/45.58
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	2.9%	10.3%	54.9%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	4/22 (18%)	13/21 (62%)
FIRST INCIDENCE	---	---	---	592	731 (T)	610
STATISTICAL TESTS						
LIFE TABLE	P<0.001 **	(e)	(e)	P=0.462	P=0.046 *	P<0.001 **
POLY 3	P<0.001 **	(e)	(e)	P=0.474	P=0.057	P<0.001 **
POLY 1.5	P<0.001 **	(e)	(e)	P=0.484	P=0.059	P<0.001 **
POLY 6	P<0.001 **	(e)	(e)	P=0.461	P=0.055	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	(e)	(e)	P=0.508	P=0.046 *	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	(e)	(e)	P=0.500	P=0.059	P<0.001 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Liver						
Hepatocellular Adenoma						
TUMOR RATES						
OVERALL (a)	0/53 (0%)	0/54 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	6/53 (11%)
POLY-3 RATE (b)	0/39.55	0/34.61	0/38.75	0/34.16	0/39.00	6/43.02
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	0.0%	14.0%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	0/22 (0%)	3/21 (14%)
FIRST INCIDENCE	---	---	---	---	---	648
STATISTICAL TESTS						
LIFE TABLE	P<0.001 **	(e)	(e)	(e)	(e)	P=0.014 *
POLY 3	P<0.001 **	(e)	(e)	(e)	(e)	P=0.020 *
POLY 1.5	P<0.001 **	(e)	(e)	(e)	(e)	P=0.019 *
POLY 6	P<0.001 **	(e)	(e)	(e)	(e)	P=0.018 *
LOGISTIC REGRESSION	P<0.001 **	(e)	(e)	(e)	(e)	P=0.018 *
COCH-ARM / FISHERS	P<0.001 **	(e)	(e)	(e)	(e)	P=0.013 *
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

	Females					
Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Lung						
Cystic Keratinizing Epithelioma						
TUMOR RATES						
OVERALL (a)	0/53 (0%)	0/54 (0%)	0/53 (0%)	0/52 (0%)	0/53 (0%)	9/52 (17%)
POLY-3 RATE (b)	0/39.55	0/34.61	0/38.75	0/33.71	0/39.00	9/42.72
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	0.0%	21.1%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	0/22 (0%)	4/21 (19%)
FIRST INCIDENCE	---	---	---	---	---	610
STATISTICAL TESTS						
LIFE TABLE	P<0.001 **	(e)	(e)	(e)	(e)	P=0.002 **
POLY 3	P<0.001 **	(e)	(e)	(e)	(e)	P=0.002 **
POLY 1.5	P<0.001 **	(e)	(e)	(e)	(e)	P=0.002 **
POLY 6	P<0.001 **	(e)	(e)	(e)	(e)	P=0.002 **
LOGISTIC REGRESSION	P<0.001 **	(e)	(e)	(e)	(e)	P=0.003 **
COCH-ARM / FISHERS	P<0.001 **	(e)	(e)	(e)	(e)	P<0.001 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)

	Females					
Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Mammary Gland						
Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	2/53 (4%)	0/54 (0%)	1/53 (2%)	0/53 (0%)	0/53 (0%)	1/53 (2%)
POLY-3 RATE (b)	2/39.90	0/34.61	1/38.75	0/34.16	0/39.00	1/42.60
POLY-3 PERCENT (g)	5.0%	0.0%	2.6%	0.0%	0.0%	2.4%
TERMINAL (d)	1/25 (4%)	0/21 (0%)	1/23 (4%)	0/19 (0%)	0/22 (0%)	1/21 (5%)
FIRST INCIDENCE	631	---	731 (T)	---	---	731 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.591N	P=0.305N	P=0.532N	P=0.317N	P=0.260N	P=0.535N
POLY 3	P=0.555N	P=0.270N	P=0.510N	P=0.273N	P=0.242N	P=0.477N
POLY 1.5	P=0.570N	P=0.254N	P=0.511N	P=0.258N	P=0.240N	P=0.479N
POLY 6	P=0.541N	P=0.288N	P=0.512N	P=0.293N	P=0.247N	P=0.488N
LOGISTIC REGRESSION	P=0.555N	P=0.263N	P=0.507N	P=0.267N	P=0.240N	P=0.479N
COCH-ARM / FISHERS	P=0.595N	P=0.243N	P=0.500N	P=0.248N	P=0.248N	P=0.500N
ORDER RESTRICTED	P=0.110N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

	Females					
Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Mammary Gland Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	4/53 (8%)	8/54 (15%)	4/53 (8%)	2/53 (4%)	2/53 (4%)	0/53 (0%)
POLY-3 RATE (b)	4/40.42	8/37.03	4/39.08	2/35.28	2/39.22	0/42.60
POLY-3 PERCENT (g)	9.9%	21.6%	10.2%	5.7%	5.1%	0.0%
TERMINAL (d)	2/25 (8%)	4/21 (19%)	1/23 (4%)	0/19 (0%)	1/22 (5%)	0/21 (0%)
FIRST INCIDENCE	469	241	659	338	673	---
STATISTICAL TESTS						
LIFE TABLE	P=0.008N**	P=0.127	P=0.616	P=0.439N	P=0.377N	P=0.077N
POLY 3	P=0.004N**	P=0.132	P=0.626	P=0.401N	P=0.350N	P=0.053N
POLY 1.5	P=0.004N**	P=0.155	P=0.624	P=0.374N	P=0.345N	P=0.054N
POLY 6	P=0.004N**	P=0.109	P=0.627	P=0.436N	P=0.360N	P=0.057N
LOGISTIC REGRESSION	P=0.006N**	P=0.184	P=0.633	P=0.327N	P=0.340N	P=0.060N
COCH-ARM / FISHERS	P=0.006N**	P=0.189	P=0.642N	P=0.339N	P=0.339N	P=0.059N
ORDER RESTRICTED	P=0.005N**	(e)	(e)	(e)	(e)	(e)

	Females					
Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Mammary Gland Carcinoma or Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	6/53 (11%)	8/54 (15%)	5/53 (9%)	2/53 (4%)	2/53 (4%)	1/53 (2%)
POLY-3 RATE (b)	6/40.77	8/37.03	5/39.08	2/35.28	2/39.22	1/42.60
POLY-3 PERCENT (g)	14.7%	21.6%	12.8%	5.7%	5.1%	2.4%
TERMINAL (d)	3/25 (12%)	4/21 (19%)	2/23 (9%)	0/19 (0%)	1/22 (5%)	1/21 (5%)
FIRST INCIDENCE	469	241	659	338	673	731 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.011N*	P=0.278	P=0.538N	P=0.232N	P=0.168N	P=0.077N
POLY 3	P=0.005N**	P=0.310	P=0.530N	P=0.182N	P=0.143N	P=0.048N*
POLY 1.5	P=0.006N**	P=0.350	P=0.528N	P=0.160N	P=0.139N	P=0.048N*
POLY 6	P=0.005N**	P=0.266	P=0.536N	P=0.214N	P=0.151N	P=0.053N
LOGISTIC REGRESSION	P=0.007N**	P=0.385	P=0.515N	P=0.137N	P=0.137N	P=0.051N
COCH-ARM / FISHERS	P=0.009N**	P=0.402	P=0.500N	P=0.135N	P=0.135N	P=0.056N
ORDER RESTRICTED	P=0.009N**	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Mammary Gland Fibroadenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	33/53 (62%)	40/54 (74%)	34/53 (64%)	29/53 (55%)	36/53 (68%)	24/53 (45%)
POLY-3 RATE (b)	33/46.50	40/48.95	34/45.82	29/41.25	36/48.31	24/47.04
POLY-3 PERCENT (g)	71.0%	81.7%	74.2%	70.3%	74.5%	51.0%
TERMINAL (d)	16/25 (64%)	16/21 (76%)	16/23 (70%)	12/19 (63%)	15/22 (68%)	12/21 (57%)
FIRST INCIDENCE	185	241	236	453	141	396
STATISTICAL TESTS						
LIFE TABLE	P=0.021N*	P=0.048 *	P=0.404	P=0.338	P=0.256	P=0.174N
POLY 3	P<0.001N**	P=0.147	P=0.452	P=0.570N	P=0.435	P=0.031N*
POLY 1.5	P<0.001N**	P=0.129	P=0.418	P=0.468N	P=0.401	P=0.033N*
POLY 6	P=0.002N**	P=0.183	P=0.498	P=0.559	P=0.453	P=0.041N*
LOGISTIC REGRESSION	P=0.002N**	P=0.104	P=0.445	P=0.424N	P=0.337	P=0.043N*
COCH-ARM / FISHERS	P=0.009N**	P=0.135	P=0.500	P=0.277N	P=0.342	P=0.059N
ORDER RESTRICTED	P=0.002N**	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Mammary Gland Fibroma, Fibroadenoma or Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	35/53 (66%)	40/54 (74%)	35/53 (66%)	29/53 (55%)	36/53 (68%)	24/53 (45%)
POLY-3 RATE (b)	35/46.86	40/48.95	35/45.82	29/41.25	36/48.31	24/47.04
POLY-3 PERCENT (g)	74.7%	81.7%	76.4%	70.3%	74.5%	51.0%
TERMINAL (d)	17/25 (68%)	16/21 (76%)	17/23 (74%)	12/19 (63%)	15/22 (68%)	12/21 (57%)
FIRST INCIDENCE	185	241	236	453	141	396
STATISTICAL TESTS						
LIFE TABLE	P=0.013N*	P=0.079	P=0.454	P=0.435	P=0.352	P=0.109N
POLY 3	P<0.001N**	P=0.269	P=0.522	P=0.407N	P=0.589N	P=0.010N*
POLY 1.5	P<0.001N**	P=0.244	P=0.493	P=0.308N	P=0.572	P=0.011N*
POLY 6	P<0.001N**	P=0.311	P=0.554	P=0.500N	P=0.591N	P=0.015N*
LOGISTIC REGRESSION	P<0.001N**	P=0.192	P=0.523	P=0.275N	P=0.495	P=0.016N*
COCH-ARM / FISHERS	P=0.004N**	P=0.243	P=0.581N	P=0.160N	P=0.500	P=0.025N*
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	35/53 (66%)	43/54 (80%)	37/53 (70%)	31/53 (58%)	37/53 (70%)	24/53 (45%)
POLY-3 RATE (b)	35/46.86	43/49.90	37/46.14	31/42.36	37/48.53	24/47.04
POLY-3 PERCENT (g)	74.7%	86.2%	80.2%	73.2%	76.2%	51.0%
TERMINAL (d)	17/25 (68%)	17/21 (81%)	17/23 (74%)	12/19 (63%)	15/22 (68%)	12/21 (57%)
FIRST INCIDENCE	185	241	236	338	141	396
STATISTICAL TESTS						
LIFE TABLE	P=0.007N**	P=0.034 *	P=0.344	P=0.318	P=0.303	P=0.109N
POLY 3	P<0.001N**	P=0.107	P=0.343	P=0.533N	P=0.526	P=0.010N*
POLY 1.5	P<0.001N**	P=0.089	P=0.314	P=0.441N	P=0.488	P=0.011N*
POLY 6	P<0.001N**	P=0.135	P=0.389	P=0.606	P=0.546	P=0.015N*
LOGISTIC REGRESSION	P<0.001N**	P=0.062	P=0.349	P=0.411N	P=0.412	P=0.016N*
COCH-ARM / FISHERS	P<0.001N**	P=0.086	P=0.418	P=0.274N	P=0.418	P=0.025N*
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	2/54 (4%)	1/53 (2%)	0/53 (0%)	4/53 (8%)	10/53 (19%)
POLY-3 RATE (b)	1/40.42	2/34.91	1/39.25	0/34.16	4/39.40	10/45.45
POLY-3 PERCENT (g)	2.5%	5.7%	2.6%	0.0%	10.2%	22.0%
TERMINAL (d)	0/25 (0%)	1/21 (5%)	0/23 (0%)	0/19 (0%)	1/22 (5%)	2/21 (10%)
FIRST INCIDENCE	366	647	578	---	659	546
STATISTICAL TESTS						
LIFE TABLE	P<0.001 **	P=0.444	P=0.757N	P=0.496N	P=0.166	P=0.009 **
POLY 3	P<0.001 **	P=0.449	P=0.755	P=0.533N	P=0.169	P=0.007 **
POLY 1.5	P<0.001 **	P=0.471	P=0.753	P=0.520N	P=0.173	P=0.006 **
POLY 6	P<0.001 **	P=0.428	P=0.756	P=0.549N	P=0.165	P=0.007 **
LOGISTIC REGRESSION	P<0.001 **	P=0.527	P=0.725N	P=0.436N	P=0.180	P=0.002 **
COCH-ARM / FISHERS	P<0.001 **	P=0.507	P=0.752N	P=0.500N	P=0.181	P=0.004 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	0 NG/KG	3 NG/KG	10 NG/KG	Females 22 NG/KG	46 NG/KG	100 NG/KG
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	2/54 (4%)	1/53 (2%)	0/53 (0%)	4/53 (8%)	10/53 (19%)
POLY-3 RATE (b)	1/40.42	2/34.91	1/39.25	0/34.16	4/39.40	10/45.45
POLY-3 PERCENT (g)	2.5%	5.7%	2.6%	0.0%	10.2%	22.0%
TERMINAL (d)	0/25 (0%)	1/21 (5%)	0/23 (0%)	0/19 (0%)	1/22 (5%)	2/21 (10%)
FIRST INCIDENCE	366	647	578	---	659	546
STATISTICAL TESTS						
LIFE TABLE	P<0.001 **	P=0.444	P=0.757N	P=0.496N	P=0.166	P=0.009 **
POLY 3	P<0.001 **	P=0.449	P=0.755	P=0.533N	P=0.169	P=0.007 **
POLY 1.5	P<0.001 **	P=0.471	P=0.753	P=0.520N	P=0.173	P=0.006 **
POLY 6	P<0.001 **	P=0.428	P=0.756	P=0.549N	P=0.165	P=0.007 **
LOGISTIC REGRESSION	P<0.001 **	P=0.527	P=0.725N	P=0.436N	P=0.180	P=0.002 **
COCH-ARM / FISHERS	P<0.001 **	P=0.507	P=0.752N	P=0.500N	P=0.181	P=0.004 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	Females 22 NG/KG	46 NG/KG	100 NG/KG
Oral Mucosa Squamous Cell Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	2/54 (4%)	1/53 (2%)	0/53 (0%)	4/53 (8%)	10/53 (19%)
POLY-3 RATE (b)	1/40.42	2/34.91	1/39.25	0/34.16	4/39.40	10/45.45
POLY-3 PERCENT (g)	2.5%	5.7%	2.6%	0.0%	10.2%	22.0%
TERMINAL (d)	0/25 (0%)	1/21 (5%)	0/23 (0%)	0/19 (0%)	1/22 (5%)	2/21 (10%)
FIRST INCIDENCE	366	647	578	---	659	546
STATISTICAL TESTS						
LIFE TABLE	P<0.001 **	P=0.444	P=0.757N	P=0.496N	P=0.166	P=0.009 **
POLY 3	P<0.001 **	P=0.449	P=0.755	P=0.533N	P=0.169	P=0.007 **
POLY 1.5	P<0.001 **	P=0.471	P=0.753	P=0.520N	P=0.173	P=0.006 **
POLY 6	P<0.001 **	P=0.428	P=0.756	P=0.549N	P=0.165	P=0.007 **
LOGISTIC REGRESSION	P<0.001 **	P=0.527	P=0.725N	P=0.436N	P=0.180	P=0.002 **
COCH-ARM / FISHERS	P<0.001 **	P=0.507	P=0.752N	P=0.500N	P=0.181	P=0.004 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

				Females		
Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Pancreas Carcinoma						
TUMOR RATES						
OVERALL (a)	0/51 (0%)	0/54 (0%)	0/52 (0%)	0/53 (0%)	0/52 (0%)	2/51 (4%)
POLY-3 RATE (b)	0/38.86	0/34.61	0/38.64	0/34.16	0/38.45	2/41.18
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	0.0%	4.9%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	0/22 (0%)	1/21 (5%)
FIRST INCIDENCE	---	---	---	---	---	641
STATISTICAL TESTS						
LIFE TABLE	P=0.014 *	(e)	(e)	(e)	(e)	P=0.223
POLY 3	P=0.011 *	(e)	(e)	(e)	(e)	P=0.250
POLY 1.5	P=0.011 *	(e)	(e)	(e)	(e)	P=0.249
POLY 6	P=0.011 *	(e)	(e)	(e)	(e)	P=0.244
LOGISTIC REGRESSION	P=0.014 *	(e)	(e)	(e)	(e)	P=0.247
COCH-ARM / FISHERS	P=0.010 *	(e)	(e)	(e)	(e)	P=0.248
ORDER RESTRICTED	P=0.011 *	(e)	(e)	(e)	(e)	(e)

				Females		
Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Pancreas Carcinoma or Adenoma						
TUMOR RATES						
OVERALL (a)	0/51 (0%)	0/54 (0%)	0/52 (0%)	0/53 (0%)	0/52 (0%)	3/51 (6%)
POLY-3 RATE (b)	0/38.86	0/34.61	0/38.64	0/34.16	0/38.45	3/41.18
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	0.0%	7.3%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	0/22 (0%)	2/21 (10%)
FIRST INCIDENCE	---	---	---	---	---	641
STATISTICAL TESTS						
LIFE TABLE	P<0.001 **	(e)	(e)	(e)	(e)	P=0.104
POLY 3	P<0.001 **	(e)	(e)	(e)	(e)	P=0.129
POLY 1.5	P<0.001 **	(e)	(e)	(e)	(e)	P=0.128
POLY 6	P<0.001 **	(e)	(e)	(e)	(e)	P=0.123
LOGISTIC REGRESSION	P=0.002 **	(e)	(e)	(e)	(e)	P=0.125
COCH-ARM / FISHERS	P<0.001 **	(e)	(e)	(e)	(e)	P=0.121
ORDER RESTRICTED	P=0.002 **	(e)	(e)	(e)	(e)	(e)

Dose	Females 0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Pituitary Gland: Pars Distalis or Unspecified Site						
Adenoma						
TUMOR RATES						
OVERALL (a)	25/53 (47%)	20/54 (37%)	26/52 (50%)	15/53 (28%)	20/53 (38%)	11/52 (21%)
POLY-3 RATE (b)	25/42.82	20/36.20	26/40.49	15/36.38	20/42.25	11/44.01
POLY-3 PERCENT (g)	58.4%	55.3%	64.2%	41.2%	47.3%	25.0%
TERMINAL (d)	15/25 (60%)	16/21 (76%)	15/23 (65%)	9/19 (47%)	10/22 (46%)	4/21 (19%)
FIRST INCIDENCE	474	604	550	545	444	604
STATISTICAL TESTS						
LIFE TABLE	P=0.004N**	P=0.542N	P=0.397	P=0.253N	P=0.356N	P=0.016N*
POLY 3	P<0.001N**	P=0.478N	P=0.369	P=0.087N	P=0.202N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.334N	P=0.372	P=0.056N	P=0.203N	P<0.001N**
POLY 6	P<0.001N**	P=0.545	P=0.363	P=0.146N	P=0.212N	P<0.001N**
LOGISTIC REGRESSION	P<0.001N**	P=0.503N	P=0.420	P=0.102N	P=0.216N	P<0.001N**
COCH-ARM / FISHERS	P=0.003N**	P=0.193N	P=0.462	P=0.035N*	P=0.216N	P=0.004N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)	(e)	(e)

Dose	Females 0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Pituitary Gland: Pars Intermedia						
Adenoma						
TUMOR RATES						
OVERALL (a)	2/53 (4%)	0/54 (0%)	0/52 (0%)	0/53 (0%)	0/53 (0%)	0/52 (0%)
POLY-3 RATE (b)	2/39.60	0/34.61	0/38.01	0/34.16	0/39.00	0/42.44
POLY-3 PERCENT (g)	5.1%	0.0%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	1/25 (4%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	0/22 (0%)	0/21 (0%)
FIRST INCIDENCE	717	---	---	---	---	---
STATISTICAL TESTS						
LIFE TABLE	P=0.259N	P=0.277N	P=0.245N	P=0.311N	P=0.272N	P=0.268N
POLY 3	P=0.226N	P=0.268N	P=0.246N	P=0.271N	P=0.240N	P=0.222N
POLY 1.5	P=0.235N	P=0.253N	P=0.248N	P=0.257N	P=0.239N	P=0.225N
POLY 6	P=0.216N	P=0.284N	P=0.244N	P=0.290N	P=0.244N	P=0.226N
LOGISTIC REGRESSION	P=0.243N	P=0.286N	P=0.242N	P=0.303N	P=0.254N	P=0.246N
COCH-ARM / FISHERS	P=0.250N	P=0.243N	P=0.252N	P=0.248N	P=0.248N	P=0.252N
ORDER RESTRICTED	P=0.007N**	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Skin Fibroma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	0/54 (0%)	2/53 (4%)	0/53 (0%)	0/53 (0%)	1/53 (2%)
POLY-3 RATE (b)	1/40.13	0/34.61	2/39.56	0/34.16	0/39.00	1/42.65
POLY-3 PERCENT (g)	2.5%	0.0%	5.1%	0.0%	0.0%	2.3%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	0/22 (0%)	0/21 (0%)
FIRST INCIDENCE	548	---	578	---	---	717
STATISTICAL TESTS						
LIFE TABLE	P=0.605N	P=0.505N	P=0.509	P=0.515N	P=0.490N	P=0.747N
POLY 3	P=0.612N	P=0.529N	P=0.495	P=0.532N	P=0.506N	P=0.747N
POLY 1.5	P=0.628N	P=0.516N	P=0.491	P=0.519N	P=0.503N	P=0.748N
POLY 6	P=0.601N	P=0.544N	P=0.499	P=0.548N	P=0.511N	P=0.755N
LOGISTIC REGRESSION	P=0.653	P=0.475N	P=0.511	P=0.479N	P=0.497N	P=0.753
COCH-ARM / FISHERS	P=0.650N	P=0.495N	P=0.500	P=0.500N	P=0.500N	P=0.752N
ORDER RESTRICTED	P=0.480N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Skin Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	0/54 (0%)	3/53 (6%)	1/53 (2%)	0/53 (0%)	1/53 (2%)
POLY-3 RATE (b)	1/40.13	0/34.61	3/39.97	1/34.16	0/39.00	1/42.65
POLY-3 PERCENT (g)	2.5%	0.0%	7.5%	2.9%	0.0%	2.3%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	1/19 (5%)	0/22 (0%)	0/21 (0%)
FIRST INCIDENCE	548	---	578	731 (T)	---	717
STATISTICAL TESTS						
LIFE TABLE	P=0.451N	P=0.505N	P=0.313	P=0.721	P=0.490N	P=0.747N
POLY 3	P=0.439N	P=0.529N	P=0.303	P=0.724	P=0.506N	P=0.747N
POLY 1.5	P=0.458N	P=0.516N	P=0.298	P=0.740	P=0.503N	P=0.748N
POLY 6	P=0.430N	P=0.544N	P=0.309	P=0.704	P=0.511N	P=0.755N
LOGISTIC REGRESSION	P=0.482N	P=0.475N	P=0.314	P=0.755	P=0.497N	P=0.753
COCH-ARM / FISHERS	P=0.493N	P=0.495N	P=0.309	P=0.752N	P=0.500N	P=0.752N
ORDER RESTRICTED	P=0.459N	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	0 NG/KG	3 NG/KG	10 NG/KG	Females 22 NG/KG	46 NG/KG	100 NG/KG
Skin						
Schwannoma Malignant						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	0/54 (0%)	0/53 (0%)	2/53 (4%)	0/53 (0%)	1/53 (2%)
POLY-3 RATE (b)	1/39.67	0/34.61	0/38.75	2/35.78	0/39.00	1/43.05
POLY-3 PERCENT (g)	2.5%	0.0%	0.0%	5.6%	0.0%	2.3%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	0/22 (0%)	0/21 (0%)
FIRST INCIDENCE	701	---	---	380	---	599
STATISTICAL TESTS						
LIFE TABLE	P=0.559	P=0.539N	P=0.500N	P=0.459	P=0.515N	P=0.747N
POLY 3	P=0.576	P=0.527N	P=0.505N	P=0.464	P=0.503N	P=0.743N
POLY 1.5	P=0.563	P=0.515N	P=0.506N	P=0.479	P=0.502N	P=0.745N
POLY 6	P=0.577	P=0.541N	P=0.505N	P=0.443	P=0.507N	P=0.748N
LOGISTIC REGRESSION	P=0.441	P=0.536N	P=0.504N	P=0.552	P=0.505N	P=0.763
COCH-ARM / FISHERS	P=0.519	P=0.495N	P=0.500N	P=0.500	P=0.500N	P=0.752N
ORDER RESTRICTED	P=0.501	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	Females 22 NG/KG	46 NG/KG	100 NG/KG
Stomach, Forestomach						
Squamous Cell Carcinoma or Papilloma Squamous						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/53 (2%)	0/54 (0%)	0/53 (0%)	0/53 (0%)	2/53 (4%)	1/53 (2%)
POLY-3 RATE (b)	1/39.86	0/34.61	0/38.75	0/34.16	2/39.21	1/42.60
POLY-3 PERCENT (g)	2.5%	0.0%	0.0%	0.0%	5.1%	2.4%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	0/22 (0%)	1/21 (5%)
FIRST INCIDENCE	646	---	---	---	701	731 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.274	P=0.570N	P=0.523N	P=0.586N	P=0.472	P=0.738
POLY 3	P=0.326	P=0.528N	P=0.506N	P=0.531N	P=0.494	P=0.746N
POLY 1.5	P=0.310	P=0.515N	P=0.506N	P=0.518N	P=0.497	P=0.747N
POLY 6	P=0.328	P=0.542N	P=0.506N	P=0.547N	P=0.488	P=0.754N
LOGISTIC REGRESSION	P=0.299	P=0.508N	P=0.502N	P=0.511N	P=0.495	P=0.749N
COCH-ARM / FISHERS	P=0.259	P=0.495N	P=0.500N	P=0.500N	P=0.500	P=0.752N
ORDER RESTRICTED	P=0.249	(e)	(e)	(e)	(e)	(e)

	Females					
Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Thyroid Gland: C-Cell Adenoma						
TUMOR RATES						
OVERALL (a)	20/52 (38%)	15/54 (28%)	17/53 (32%)	16/51 (31%)	13/53 (25%)	11/52 (21%)
POLY-3 RATE (b)	20/42.85	15/37.10	17/39.42	16/37.06	13/41.12	11/43.05
POLY-3 PERCENT (g)	46.7%	40.4%	43.1%	43.2%	31.6%	25.6%
TERMINAL (d)	10/25 (40%)	10/21 (48%)	13/23 (57%)	8/19 (42%)	8/22 (36%)	6/21 (29%)
FIRST INCIDENCE	474	462	626	338	486	638
STATISTICAL TESTS						
LIFE TABLE	P=0.048N*	P=0.422N	P=0.430N	P=0.551	P=0.180N	P=0.091N
POLY 3	P=0.010N*	P=0.366N	P=0.459N	P=0.464N	P=0.111N	P=0.030N*
POLY 1.5	P=0.015N*	P=0.268N	P=0.413N	P=0.382N	P=0.099N	P=0.028N*
POLY 6	P=0.010N*	P=0.499N	P=0.533N	P=0.579N	P=0.139N	P=0.043N*
LOGISTIC REGRESSION	P=0.014N*	P=0.286N	P=0.338N	P=0.385N	P=0.093N	P=0.028N*
COCH-ARM / FISHERS	P=0.047N*	P=0.168N	P=0.316N	P=0.292N	P=0.092N	P=0.043N*
ORDER RESTRICTED	P=0.021N*	(e)	(e)	(e)	(e)	(e)

	Females					
Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
Thyroid Gland: C-Cell Carcinoma						
TUMOR RATES						
OVERALL (a)	1/52 (2%)	1/54 (2%)	0/53 (0%)	0/51 (0%)	2/53 (4%)	0/52 (0%)
POLY-3 RATE (b)	1/38.90	1/35.04	0/38.75	0/33.58	2/39.00	0/41.66
POLY-3 PERCENT (g)	2.6%	2.9%	0.0%	0.0%	5.1%	0.0%
TERMINAL (d)	1/25 (4%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	2/22 (9%)	0/21 (0%)
FIRST INCIDENCE	731 (T)	604	---	---	731 (T)	---
STATISTICAL TESTS						
LIFE TABLE	P=0.506N	P=0.712	P=0.517N	P=0.555N	P=0.455	P=0.535N
POLY 3	P=0.468N	P=0.738	P=0.501N	P=0.529N	P=0.501	P=0.486N
POLY 1.5	P=0.475N	P=0.750	P=0.502N	P=0.519N	P=0.504	P=0.487N
POLY 6	P=0.472N	P=0.724	P=0.501N	P=0.543N	P=0.493	P=0.492N
LOGISTIC REGRESSION	P=0.474N	P=0.749	(e)	(e)	P=0.455	(e)
COCH-ARM / FISHERS	P=0.511N	P=0.743N	P=0.495N	P=0.505N	P=0.507	P=0.500N
ORDER RESTRICTED	P=0.306N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Thyroid Gland: C-Cell Carcinoma or Adenoma						
TUMOR RATES						
OVERALL (a)	21/52 (40%)	15/54 (28%)	17/53 (32%)	16/51 (31%)	14/53 (26%)	11/52 (21%)
POLY-3 RATE (b)	21/42.85	15/37.10	17/39.42	16/37.06	14/41.12	11/43.05
POLY-3 PERCENT (g)	49.0%	40.4%	43.1%	43.2%	34.0%	25.6%
TERMINAL (d)	11/25 (44%)	10/21 (48%)	13/23 (57%)	8/19 (42%)	9/22 (41%)	6/21 (29%)
FIRST INCIDENCE	474	462	626	338	486	638
STATISTICAL TESTS						
LIFE TABLE	P=0.044N*	P=0.354N	P=0.358N	P=0.534N	P=0.188N	P=0.066N
POLY 3	P=0.008N**	P=0.288N	P=0.374N	P=0.380N	P=0.115N	P=0.017N*
POLY 1.5	P=0.013N*	P=0.202N	P=0.333N	P=0.304N	P=0.101N	P=0.016N*
POLY 6	P=0.008N**	P=0.415N	P=0.446N	P=0.495N	P=0.145N	P=0.025N*
LOGISTIC REGRESSION	P=0.012N*	P=0.225N	P=0.264N	P=0.316N	P=0.095N	P=0.016N*
COCH-ARM / FISHERS	P=0.043N*	P=0.122N	P=0.247N	P=0.227N	P=0.095N	P=0.027N*
ORDER RESTRICTED	P=0.011N*	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Uterus Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	2/54 (4%)	0/53 (0%)	1/53 (2%)	2/53 (4%)	1/53 (2%)
POLY-3 RATE (b)	0/39.55	2/34.61	0/38.75	1/34.16	2/39.00	1/42.66
POLY-3 PERCENT (g)	0.0%	5.8%	0.0%	2.9%	5.1%	2.3%
TERMINAL (d)	0/25 (0%)	2/21 (10%)	0/23 (0%)	1/19 (5%)	2/22 (9%)	0/21 (0%)
FIRST INCIDENCE	---	731 (T)	---	731 (T)	731 (T)	716
STATISTICAL TESTS						
LIFE TABLE	P=0.421	P=0.200	(e)	P=0.445	P=0.210	P=0.492
POLY 3	P=0.489	P=0.208	(e)	P=0.471	P=0.233	P=0.515
POLY 1.5	P=0.485	P=0.221	(e)	P=0.483	P=0.235	P=0.513
POLY 6	P=0.476	P=0.195	(e)	P=0.456	P=0.229	P=0.511
LOGISTIC REGRESSION	P=0.443	P=0.200	(e)	P=0.445	P=0.210	P=0.501
COCH-ARM / FISHERS	P=0.441	P=0.252	(e)	P=0.500	P=0.248	P=0.500
ORDER RESTRICTED	P=0.246	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Uterus Polyp Stromal						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	11/53 (21%)	7/54 (13%)	4/53 (8%)	11/53 (21%)	10/53 (19%)	8/53 (15%)
POLY-3 RATE (b)	11/40.11	7/35.74	4/39.04	11/36.29	10/40.43	8/44.05
POLY-3 PERCENT (g)	27.4%	19.6%	10.3%	30.3%	24.7%	18.2%
TERMINAL (d)	8/25 (32%)	5/21 (24%)	2/23 (9%)	6/19 (32%)	5/22 (23%)	3/21 (14%)
FIRST INCIDENCE	645	526	659	557	590	598
STATISTICAL TESTS						
LIFE TABLE	P=0.531	P=0.361N	P=0.064N	P=0.314	P=0.589	P=0.400N
POLY 3	P=0.404N	P=0.296N	P=0.045N*	P=0.490	P=0.492N	P=0.223N
POLY 1.5	P=0.452N	P=0.257N	P=0.048N*	P=0.531	P=0.496N	P=0.240N
POLY 6	P=0.386N	P=0.342N	P=0.043N*	P=0.445	P=0.491N	P=0.225N
LOGISTIC REGRESSION	P=0.439N	P=0.359N	P=0.045N*	P=0.395	P=0.527N	P=0.253N
COCH-ARM / FISHERS	P=0.497	P=0.207N	P=0.046N*	P=0.594N	P=0.500N	P=0.307N
ORDER RESTRICTED	P=0.245N	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
Uterus Squamous Cell Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	0/54 (0%)	0/53 (0%)	0/53 (0%)	5/53 (9%)	0/53 (0%)
POLY-3 RATE (b)	0/39.55	0/34.61	0/38.75	0/34.16	5/40.55	0/42.60
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	12.3%	0.0%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	0/22 (0%)	0/21 (0%)
FIRST INCIDENCE	---	---	---	---	589	---
STATISTICAL TESTS						
LIFE TABLE	P=0.300	(e)	(e)	(e)	P=0.035 *	(e)
POLY 3	P=0.337	(e)	(e)	(e)	P=0.032 *	(e)
POLY 1.5	P=0.318	(e)	(e)	(e)	P=0.031 *	(e)
POLY 6	P=0.328	(e)	(e)	(e)	P=0.033 *	(e)
LOGISTIC REGRESSION	P=0.259	(e)	(e)	(e)	P=0.033 *	(e)
COCH-ARM / FISHERS	P=0.247	(e)	(e)	(e)	P=0.028 *	(e)
ORDER RESTRICTED	P=0.033 *	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	Females 22 NG/KG	46 NG/KG	100 NG/KG
All Organs Hemangiosarcoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	0/54 (0%)	0/53 (0%)	0/53 (0%)	2/53 (4%)	0/53 (0%)
POLY-3 RATE (b)	0/39.55	0/34.61	0/38.75	0/34.16	2/39.00	0/42.60
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	5.1%	0.0%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	2/22 (9%)	0/21 (0%)
FIRST INCIDENCE	---	---	---	---	731 (T)	---
STATISTICAL TESTS						
LIFE TABLE	P=0.446	(e)	(e)	(e)	P=0.210	(e)
POLY 3	P=0.544	(e)	(e)	(e)	P=0.233	(e)
POLY 1.5	P=0.527	(e)	(e)	(e)	P=0.235	(e)
POLY 6	P=0.542	(e)	(e)	(e)	P=0.229	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	P=0.210	(e)
COCH-ARM / FISHERS	P=0.461	(e)	(e)	(e)	P=0.248	(e)
ORDER RESTRICTED	P=0.183	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	Females 22 NG/KG	46 NG/KG	100 NG/KG
All Organs Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/53 (0%)	1/54 (2%)	1/53 (2%)	0/53 (0%)	1/53 (2%)	2/53 (4%)
POLY-3 RATE (b)	0/39.55	1/35.31	1/39.12	0/34.16	1/39.64	2/42.60
POLY-3 PERCENT (g)	0.0%	2.8%	2.6%	0.0%	2.5%	4.7%
TERMINAL (d)	0/25 (0%)	0/21 (0%)	0/23 (0%)	0/19 (0%)	0/22 (0%)	2/21 (10%)
FIRST INCIDENCE	---	490	626	---	518	731 (T)
STATISTICAL TESTS						
LIFE TABLE	P=0.170	P=0.491	P=0.484	(e)	P=0.505	P=0.200
POLY 3	P=0.172	P=0.477	P=0.498	(e)	P=0.500	P=0.254
POLY 1.5	P=0.166	P=0.488	P=0.496	(e)	P=0.500	P=0.252
POLY 6	P=0.169	P=0.467	P=0.500	(e)	P=0.499	P=0.247
LOGISTIC REGRESSION	P=0.138	P=0.536	P=0.500	(e)	P=0.504	P=0.200
COCH-ARM / FISHERS	P=0.145	P=0.505	P=0.500	(e)	P=0.500	P=0.248
ORDER RESTRICTED	P=0.107	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
All Organs Benign Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	45/53 (85%)	49/54 (91%)	45/53 (85%)	40/53 (75%)	46/53 (87%)	39/53 (74%)
POLY-3 RATE (b)	45/48.82	49/50.46	45/47.09	40/44.36	46/49.52	39/49.56
POLY-3 PERCENT (g)	92.2%	97.1%	95.6%	90.2%	92.9%	78.7%
TERMINAL (d)	23/25 (92%)	21/21 (100%)	22/23 (96%)	17/19 (90%)	21/22 (96%)	16/21 (76%)
FIRST INCIDENCE	185	241	236	338	141	396
STATISTICAL TESTS						
LIFE TABLE	P=0.093N	P=0.069	P=0.432	P=0.268	P=0.312	P=0.378N
POLY 3	P<0.001N**	P=0.232	P=0.383	P=0.511N	P=0.610	P=0.039N*
POLY 1.5	P<0.001N**	P=0.211	P=0.368	P=0.349N	P=0.575	P=0.046N*
POLY 6	P<0.001N**	P=0.301	P=0.440	P=0.657N	P=0.619	P=0.046N*
LOGISTIC REGRESSION	P<0.001N**	P=0.129	P=0.451	P=0.309N	P=0.487	P=0.043N*
COCH-ARM / FISHERS	P=0.036N*	P=0.266	P=0.607N	P=0.165N	P=0.500	P=0.115N
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)	(e)	(e)

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
All Organs Malignant Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	13/53 (25%)	19/54 (35%)	13/53 (25%)	11/53 (21%)	24/53 (45%)	34/53 (64%)
POLY-3 RATE (b)	13/43.94	19/41.93	13/42.97	11/38.84	24/42.50	34/48.63
POLY-3 PERCENT (g)	29.6%	45.3%	30.3%	28.3%	56.5%	69.9%
TERMINAL (d)	4/25 (16%)	7/21 (33%)	3/23 (13%)	3/19 (16%)	12/22 (55%)	14/21 (67%)
FIRST INCIDENCE	169	200	240	338	518	546
STATISTICAL TESTS						
LIFE TABLE	P<0.001 **	P=0.090	P=0.533	P=0.549	P=0.022 *	P<0.001 **
POLY 3	P<0.001 **	P=0.093	P=0.566	P=0.547N	P=0.008 **	P<0.001 **
POLY 1.5	P<0.001 **	P=0.121	P=0.554	P=0.493N	P=0.010 *	P<0.001 **
POLY 6	P<0.001 **	P=0.067	P=0.579	P=0.581	P=0.006 **	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	P=0.211	P=0.572N	P=0.355N	P=0.019 *	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	P=0.160	P=0.589N	P=0.408N	P=0.020 *	P<0.001 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION
Terminal Sacrifice at 105 weeks

Dose	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
			Females			
All Organs Malignant and Benign Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	47/53 (89%)	54/54 (100%)	48/53 (91%)	44/53 (83%)	50/53 (94%)	49/53 (92%)
POLY-3 RATE (b)	47/50.68	54/54.00	48/49.12	44/46.61	50/51.10	49/51.78
POLY-3 PERCENT (g)	92.7%	100.0%	97.7%	94.4%	97.9%	94.6%
TERMINAL (d)	23/25 (92%)	21/21 (100%)	22/23 (96%)	18/19 (95%)	21/22 (96%)	19/21 (91%)
FIRST INCIDENCE	169	200	236	338	141	396
STATISTICAL TESTS						
LIFE TABLE	P=0.378N	P=0.037 *	P=0.376	P=0.184	P=0.233	P=0.306
POLY 3	P=0.385N	P=0.046 *	P=0.223	P=0.535	P=0.205	P=0.504
POLY 1.5	P=0.422N	P=0.027 *	P=0.191	P=0.650	P=0.168	P=0.452
POLY 6	P=0.371N	P=0.088	P=0.314	P=0.464	P=0.298	P=0.563
LOGISTIC REGRESSION	P=0.227N	P=0.014 *	P=0.358	P=0.423N	P=0.230	P=0.469
COCH-ARM / FISHERS	P=0.502	P=0.013 *	P=0.500	P=0.289N	P=0.244	P=0.371
ORDER RESTRICTED	P=0.168	(e)	(e)	(e)	(e)	(e)

(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]
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

FINAL#2/RATS

Facility: Battelle Columbus Laboratory

Chemical CAS #: 1746-01-6

Lock Date: 06/28/01

Cage Range: All

Reasons For Removal:
25022 Accidently Killed
25019 Moribund Sacrifice
25021 Terminal Sacrifice
25018 Dosing Accident
25020 Natural Death

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]
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
DISPOSITION SUMMARY						
Animals Initially In Study	98	98	98	98	98	98
Early Deaths						
Moribund Sacrifice	19	27	15	19	17	17
Natural Death	9	6	10	15	14	15
Dosing Accident			5			
Survivors						
Terminal Sacrifice	25	21	23	19	22	21
Animals Examined Microscopically	53	54	53	53	53	53
ALIMENTARY SYSTEM						
Esophagus	(52)	(54)	(53)	(52)	(53)	(53)
Hemorrhage			1 [4.0]			
Perforation			2			
Muscularis, Inflammation	1 [2.0]	2 [2.5]	1 [2.0]	1 [2.0]	2 [1.5]	
Periesophageal Tissue, Inflammation			3 [2.7]			
Intestine Large, Colon	(52)	(53)	(53)	(53)	(53)	(51)
Parasite Metazoan	1	2	1			2
Intestine Large, Rectum	(52)	(54)	(53)	(52)	(53)	(53)
Parasite Metazoan	6	4			2	1
Intestine Small, Duodenum	(53)	(54)	(53)	(52)	(53)	(53)
Cyst						1 [2.0]
Ulcer		1 [3.0]				
Epithelium, Hyperplasia			1 [1.0]			
Liver	(53)	(54)	(53)	(53)	(53)	(53)
Angiectasis	2 [1.5]	1 [1.0]	1 [1.0]		3 [1.7]	5 [2.0]
Basophilic Focus	8	6	8	7	3	3
Basophilic Focus, Multiple	4	3	5	1	2	5
Cholangiofibrosis	1 [1.0]	1 [1.0]	2 [1.5]	1 [1.0]	11 [2.5]	31 [2.4]
Clear Cell Focus	4	1	1	2	1	1
Clear Cell Focus, Multiple	1			2	1	1
Congestion	2 [1.0]					2 [2.0]
Cytoplasmic Alteration						2 [2.0]
Degeneration, Cystic				2 [1.0]		4 [2.3]
Eosinophilic Focus	8	6	7	10	5	2
Eosinophilic Focus, Multiple	3	8	14	17	22	42
Fatty Change, Diffuse		2 [1.0]	12 [1.1]	17 [1.3]	30 [1.2]	48 [1.9]
Fatty Change, Focal	2 [1.5]	6 [1.5]	4 [1.5]	4 [1.8]	1 [1.0]	2 [2.0]
Hematopoietic Cell Proliferation	1 [2.0]	2 [1.0]	2 [1.0]	4 [1.5]	2 [2.0]	2 [2.0]
Hemorrhage					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]
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
ALIMENTARY SYSTEM - CONT						
Hepatodiaphragmatic Nodule		2		1	2	
Hyperplasia, Nodular				3	8	37
Inflammation	33 [1.1]	46 [1.2]	47 [1.1]	50 [1.4]	52 [1.2]	49 [1.3]
Mitotic Alteration				1 [2.0]	1 [2.0]	
Mixed Cell Focus	4	8	8		2	4
Mixed Cell Focus, Multiple	26	11	21	23	28	17
Necrosis	1 [2.0]	4 [2.3]	4 [2.0]	8 [2.3]	10 [1.9]	17 [2.5]
Pigmentation	4 [1.0]	9 [1.2]	34 [1.4]	48 [1.7]	52 [2.0]	53 [2.2]
Thrombosis						1 [3.0]
Toxic Hepatopathy		2 [1.0]	8 [1.3]	30 [1.2]	45 [1.8]	53 [3.5]
Artery, Inflammation, Chronic Active						2 [2.0]
Bile Duct, Cyst	3 [3.3]	1 [3.0]	2 [2.0]	2 [1.5]		21 [2.9]
Bile Duct, Fibrosis		2 [2.0]		1 [2.0]	3 [1.3]	4 [1.8]
Bile Duct, Hyperplasia	5 [1.6]	4 [1.5]	7 [1.1]	22 [1.3]	40 [1.4]	53 [2.1]
Centrilobular, Degeneration	2 [2.5]	2 [2.0]		4 [2.3]	3 [2.0]	5 [2.0]
Hepatocyte, Hypertrophy		19 [1.2]	19 [1.2]	42 [1.5]	41 [2.0]	52 [3.2]
Hepatocyte, Multinucleated			16 [1.2]	26 [1.2]	36 [1.4]	51 [1.8]
Hepatocyte, Centrilobular, Atrophy					1 [2.0]	
Oval Cell, Hyperplasia		4 [1.0]	3 [1.3]	20 [1.3]	38 [1.5]	53 [2.3]
Portal, Fibrosis					5 [1.8]	27 [2.0]
Mesentery	(2)	(2)		(1)	(6)	(8)
Metaplasia, Osseous	1 [2.0]					
Artery, Inflammation, Chronic Active		1 [3.0]			4 [2.3]	7 [2.7]
Fat, Necrosis		1 [3.0]		1 [3.0]	1 [3.0]	1 [3.0]
Vein, Thrombosis	1 [3.0]					
Oral Mucosa	(2)	(9)	(16)	(16)	(22)	(29)
Gingival, Hyperplasia, Squamous	1 [4.0]	7 [1.4]	14 [1.6]	13 [1.6]	15 [2.2]	16 [2.3]
Pancreas	(51)	(54)	(52)	(53)	(52)	(51)
Hemorrhage						1 [3.0]
Inflammation, Acute				1 [4.0]		
Inflammation, Chronic Active			2 [1.5]	2 [1.0]	3 [1.3]	6 [2.0]
Necrosis				1 [3.0]		1 [2.0]
Acinus, Atrophy	1 [1.0]	2 [1.5]	4 [1.5]	4 [1.5]	4 [1.5]	9 [2.2]
Acinus, Hyperplasia	2 [2.5]			1 [2.0]	2 [2.5]	
Acinus, Vacuolization Cytoplasmic	1 [2.0]			1 [1.0]	15 [1.1]	42 [1.8]
Artery, Inflammation, Chronic Active		1 [3.0]	1 [2.0]	2 [2.5]	2 [3.0]	7 [2.3]
Salivary Glands	(51)	(54)	(52)	(50)	(51)	(52)
Atrophy				2 [2.5]	1 [2.0]	
Inflammation			2 [2.0]	3 [2.3]		1 [3.0]
Mineralization	1 [3.0]					
Stomach, Forestomach	(53)	(54)	(53)	(53)	(53)	(53)
Cyst, Squamous			1 [2.0]			
Edema				1 [2.0]		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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
ALIMENTARY SYSTEM - CONT						
Erosion			1 [2.0]		1 [2.0]	
Hyperkeratosis	1 [1.0]	1 [1.0]	1 [1.0]	1 [3.0]	2 [2.0]	3 [2.0]
Hyperplasia, Squamous	3 [1.3]	4 [1.5]	4 [1.8]	2 [2.0]	7 [2.1]	11 [1.7]
Inflammation	1 [3.0]	1 [2.0]	2 [1.5]		2 [1.5]	5 [1.8]
Mineralization			1 [2.0]			
Necrosis						1 [1.0]
Ulcer	2 [2.5]	1 [2.0]		1 [1.0]	1 [2.0]	4 [2.5]
Stomach, Glandular	(53)	(54)	(53)	(53)	(53)	(53)
Diverticulum			1			
Erosion	1 [3.0]					
Metaplasia					1 [2.0]	
Mineralization	3 [1.3]			1 [2.0]	3 [1.7]	
Ulcer						2 [2.5]
Tooth	(16)	(16)	(12)	(13)	(14)	(18)
Peridontal Tissue, Fibrosis	1 [2.0]					
Peridontal Tissue, Inflammation	15 [1.7]	16 [1.2]	12 [1.3]	13 [1.4]	14 [1.6]	18 [1.6]
CARDIOVASCULAR SYSTEM						
Blood Vessel	(53)	(54)	(53)	(53)	(53)	(53)
Thrombosis			1 [4.0]			
Aorta, Mineralization	1 [3.0]	1 [2.0]			1 [2.0]	
Heart	(53)	(54)	(53)	(52)	(53)	(52)
Cardiomyopathy	10 [1.2]	12 [1.0]	22 [1.0]	25 [1.1]	32 [1.1]	36 [1.3]
Mineralization	1 [2.0]				1 [2.0]	
Artery, Inflammation						1 [1.0]
Artery, Mineralization		1 [2.0]				
Artery, Thrombosis						1 [2.0]
ENDOCRINE SYSTEM						
Adrenal Cortex	(53)	(54)	(53)	(53)	(53)	(53)
Angiectasis	11 [1.5]	21 [1.9]	18 [1.6]	17 [1.8]	17 [1.6]	11 [1.7]
Atrophy	2 [2.5]		4 [1.5]	5 [2.6]	5 [1.4]	27 [2.4]
Degeneration, Cystic	11 [2.5]	15 [2.1]	21 [2.1]	18 [2.3]	17 [2.2]	17 [2.3]
Hyperplasia	16 [2.0]	16 [2.2]	18 [2.4]	25 [2.3]	29 [2.3]	30 [2.5]
Hypertrophy	41 [2.1]	43 [2.0]	46 [2.0]	40 [2.2]	45 [2.1]	47 [2.4]
Inflammation, Chronic Active	1 [2.0]					
Inflammation, Suppurative	1 [1.0]					
Mineralization						1 [2.0]
Necrosis		1 [3.0]	2 [1.5]	1 [3.0]	3 [2.7]	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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
ENDOCRINE SYSTEM - CONT						
Thrombosis				1 [2.0]		
Vacuolization Cytoplasmic	11 [1.4]	7 [1.3]	12 [1.3]	21 [1.6]	18 [1.7]	15 [2.1]
Adrenal Medulla	(53)	(54)	(53)	(53)	(53)	(53)
Angiectasis		1 [2.0]	2 [2.0]	1 [2.0]		
Hyperplasia	19 [1.8]	10 [2.0]	18 [2.0]	7 [1.6]	10 [2.4]	9 [1.9]
Inflammation, Suppurative				1 [2.0]		
Islets, Pancreatic	(51)	(54)	(53)	(53)	(52)	(52)
Hyperplasia			1 [4.0]	1 [4.0]		
Parathyroid Gland	(46)	(47)	(47)	(44)	(45)	(45)
Fibrosis			1 [3.0]			
Hyperplasia	1 [2.0]					
Pituitary Gland	(53)	(54)	(52)	(53)	(53)	(52)
Angiectasis	25 [2.3]	18 [2.6]	25 [2.3]	20 [2.1]	21 [1.9]	9 [2.1]
Atypia Cellular	1 [2.0]					
Cyst	1 [2.0]	1 [3.0]				1 [2.0]
Cytoplasmic Alteration	1 [1.0]		1 [1.0]	4 [1.5]	3 [2.0]	
Developmental Malformation	1					
Inflammation, Chronic						1 [2.0]
Vacuolization Cytoplasmic		3 [1.7]	1 [2.0]	2 [1.5]	2 [2.5]	
Pars Distalis, Hyperplasia	19 [2.1]	19 [2.1]	16 [2.3]	21 [2.1]	26 [2.4]	19 [1.7]
Pars Intermedia, Hyperplasia	2 [2.5]				1 [2.0]	1 [3.0]
Thyroid Gland	(52)	(54)	(53)	(51)	(53)	(52)
Angiectasis		1 [2.0]	1 [1.0]	1 [2.0]	4 [2.0]	1 [1.0]
Cyst	1 [3.0]			1 [2.0]		1 [2.0]
Inflammation, Chronic Active			1 [2.0]			
Inflammation, Suppurative			1 [2.0]			
C-Cell, Hyperplasia	19 [1.8]	17 [2.2]	22 [2.1]	19 [2.3]	16 [1.9]	23 [1.9]
Follicular Cell, Hyperplasia	2 [2.5]	2 [2.0]				
Follicular Cell, Hypertrophy	3 [2.3]	4 [1.5]	4 [2.0]	7 [1.1]	10 [1.2]	17 [1.2]
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(50)	(52)	(53)	(52)	(51)	(53)
Hyperplasia, Basal Cell	1 [2.0]		1 [2.0]			
Inflammation	41 [1.6]	40 [1.7]	35 [1.7]	34 [1.6]	28 [1.7]	26 [1.3]
Duct, Cyst	34 [2.2]	37 [2.1]	41 [2.2]	42 [2.0]	41 [2.2]	48 [2.3]
Ovary	(51)	(53)	(53)	(53)	(53)	(53)

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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
GENITAL SYSTEM - CONT						
Atrophy	49 [4.0]	46 [4.0]	50 [4.0]	44 [4.0]	50 [4.0]	31 [3.9]
Congestion				1 [2.0]		
Cyst	14 [2.5]	16 [1.9]	13 [2.4]	15 [2.2]	14 [2.2]	13 [2.5]
Fibrosis			1 [3.0]		1 [2.0]	
Inflammation, Chronic Active				1 [3.0]		1 [3.0]
Inflammation, Suppurative				1 [4.0]	1 [2.0]	
Artery, Inflammation, Chronic Active						1 [3.0]
Corpus Luteum, Cyst		1 [3.0]				
Periovarian Tissue, Inflammation, Suppurative				1 [2.0]		
Oviduct	(2)	(1)	(2)		(1)	(1)
Inflammation	2 [3.0]	1 [3.0]	1 [2.0]			1 [4.0]
Necrosis					1 [4.0]	
Epithelium, Hyperplasia			1 [2.0]			
Uterus	(52)	(53)	(53)	(53)	(53)	(53)
Adenomyosis					1 [2.0]	
Cyst						1 [3.0]
Hemorrhage	1 [2.0]					1 [3.0]
Inflammation, Chronic Active		2 [3.0]	3 [2.7]		3 [3.3]	1 [4.0]
Inflammation, Suppurative	7 [1.9]	6 [1.8]	12 [2.4]	9 [2.1]	11 [2.3]	5 [2.2]
Metaplasia, Squamous	29 [2.0]	31 [2.0]	28 [2.5]	23 [2.5]	32 [2.5]	17 [1.7]
Necrosis				1 [4.0]		
Ulcer			1 [2.0]			
Cervix, Hyperplasia, Stromal		1 [4.0]	1 [4.0]	1 [4.0]	1 [4.0]	
Cervix, Inflammation, Suppurative					1 [3.0]	
Endometrium, Adenomyosis			1 [3.0]			
Endometrium, Hyperplasia, Cystic	30 [2.0]	33 [1.9]	35 [2.0]	27 [2.4]	31 [2.0]	19 [2.1]
Epithelium, Hyperplasia				1 [3.0]		
Serosa, Inflammation, Chronic Active			1 [3.0]			
Vagina		(1)	(1)	(3)	(3)	(1)
Cyst			1 [2.0]		1 [2.0]	
Hyperplasia, Stromal		1 [3.0]				
Inflammation				2 [4.0]		
Necrosis				1 [4.0]		
HEMATOPOIETIC SYSTEM						
Bone Marrow	(53)	(54)	(53)	(53)	(53)	(53)
Atrophy						1 [4.0]
Hyperplasia	36 [3.0]	41 [3.2]	32 [3.2]	35 [3.1]	37 [2.9]	43 [2.8]
Lymph Node	(2)	(6)	(3)	(5)	(6)	(9)
Deep Cervical, Hemorrhage				1 [3.0]		
Inguinal, Ectasia					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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
HEMATOPOIETIC SYSTEM - CONT						
Lumbar, Ectasia	1 [3.0]	2 [2.0]	1 [3.0]	2 [2.0]		
Lumbar, Hemorrhage				1 [2.0]		
Lumbar, Hyperplasia, Plasma Cell		2 [3.0]		1 [3.0]		
Lumbar, Pigmentation				1 [3.0]		
Mediastinal, Congestion					1 [2.0]	
Mediastinal, Ectasia					1 [2.0]	3 [2.0]
Mediastinal, Hemorrhage		1 [3.0]		1 [2.0]		5 [2.2]
Mediastinal, Hyperplasia					1 [4.0]	
Mediastinal, Hyperplasia, Histiocytic			1 [2.0]		1 [2.0]	1 [2.0]
Mediastinal, Hyperplasia, Lymphoid		1 [2.0]				
Mediastinal, Hyperplasia, Plasma Cell				1 [3.0]		
Mediastinal, Pigmentation			1 [2.0]			1 [2.0]
Renal, Ectasia		1 [3.0]				
Renal, Hyperplasia, Histiocytic		1 [2.0]				
Lymph Node, Mandibular	(51)	(54)	(52)	(50)	(51)	(52)
Congestion	1 [2.0]					
Ectasia					1 [2.0]	6 [2.7]
Hyperplasia, Lymphoid		3 [2.0]	3 [2.0]			2 [2.0]
Hyperplasia, Plasma Cell	25 [2.1]	31 [2.1]	23 [2.4]	22 [2.3]	15 [2.3]	16 [2.3]
Inflammation, Suppurative						1 [2.0]
Lymph Node, Mesenteric	(52)	(53)	(53)	(53)	(53)	(51)
Atrophy		1 [3.0]		1 [2.0]		
Ectasia						1 [2.0]
Hemorrhage					1 [3.0]	
Hyperplasia, Histiocytic	1 [2.0]				1 [3.0]	2 [2.5]
Hyperplasia, Plasma Cell					1 [3.0]	
Spleen	(51)	(54)	(53)	(53)	(52)	(52)
Hematopoietic Cell Proliferation	46 [1.5]	50 [1.6]	38 [1.3]	42 [1.6]	44 [1.5]	43 [1.5]
Hyperplasia, Lymphoid	1 [2.0]					4 [2.0]
Necrosis			1 [3.0]			
Pigmentation	45 [1.5]	49 [1.4]	49 [1.5]	51 [1.5]	49 [1.6]	47 [1.4]
Lymphoid Follicle, Atrophy	4 [2.3]		1 [2.0]		1 [2.0]	1 [2.0]
Thymus	(51)	(52)	(52)	(49)	(46)	(42)
Atrophy	36 [2.6]	41 [2.7]	44 [3.0]	41 [3.1]	44 [3.6]	42 [3.9]
Cyst					1 [3.0]	1 [2.0]
Hemorrhage	1 [3.0]		1 [3.0]			
Inflammation, Chronic Active					1 [3.0]	
INTEGUMENTARY SYSTEM						
Mammary Gland	(53)	(54)	(53)	(53)	(53)	(53)
Cyst	4 [2.5]	3 [2.7]		1 [3.0]	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]
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
INTEGUMENTARY SYSTEM - CONT						
Hyperplasia	25 [1.4]	21 [1.4]	24 [1.5]	22 [1.4]	18 [1.2]	16 [1.5]
Inflammation, Chronic Active					1 [3.0]	
Inflammation, Granulomatous	1 [2.0]	1 [2.0]	1 [2.0]			1 [3.0]
Skin	(53)	(54)	(53)	(53)	(53)	(53)
Cyst Epithelial Inclusion	1					2
Hemorrhage			1 [3.0]			
Hyperplasia, Squamous			1 [2.0]		1 [2.0]	
Inflammation, Chronic Active			2 [3.0]			1 [3.0]
Necrosis			1 [3.0]			
Ulcer			1 [3.0]		1 [2.0]	
Epidermis, Inflammation						1 [2.0]
MUSCULOSKELETAL SYSTEM						
Bone	(53)	(54)	(53)	(53)	(53)	(53)
Fracture						1
Maxilla, Inflammation, Focal, Suppurative		1 [2.0]				
Skeletal Muscle			(1)	(2)		
Hemorrhage				1 [3.0]		
Inflammation, Chronic Active				1 [3.0]		
NERVOUS SYSTEM						
Brain	(53)	(54)	(53)	(53)	(53)	(53)
Hemorrhage			1 [3.0]			
Hydrocephalus		1 [2.0]	1 [2.0]			
Inflammation, Suppurative					1 [3.0]	
Mineralization		1 [2.0]	1 [2.0]		2 [1.0]	2 [2.0]
Vacuolization Cytoplasmic, Focal			1 [1.0]			
Artery, Thrombosis					1 [3.0]	
Cerebellum, Developmental Malformation	1 [3.0]					
Cerebellum, Necrosis			1 [3.0]			
Glial Cell, Hyperplasia		1 [2.0]				1 [2.0]
Spinal Cord			(1)			
Gliosis			1 [2.0]			
RESPIRATORY SYSTEM						
Lung	(53)	(54)	(53)	(52)	(53)	(52)
Congestion			2 [2.5]			

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]
TOXIC EQUIVALENCY FACTOR EVALUATION (TCDD)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
RESPIRATORY SYSTEM - CONT						
Edema			2 [2.0]		1 [2.0]	
Hemorrhage		1 [2.0]				2 [2.5]
Infiltration Cellular, Histiocyte	41 [1.9]	46 [1.8]	43 [1.8]	43 [1.6]	49 [1.8]	50 [2.0]
Inflammation, Chronic Active						1 [3.0]
Inflammation, Granulomatous	2 [1.0]	1 [2.0]	2 [2.5]	2 [1.0]		
Inflammation, Suppurative	1 [3.0]			2 [1.5]		
Metaplasia, Squamous	1 [1.0]				5 [2.2]	6 [2.2]
Mineralization	1 [2.0]				1 [1.0]	1 [2.0]
Necrosis				1 [2.0]		1 [4.0]
Pigmentation		1 [1.0]				
Alveolar Epithelium, Hyperplasia	12 [1.1]					
Alveolar Epithelium, Metaplasia, Bronchiolar	2 [1.0]	19 [1.6]	33 [1.5]	35 [1.4]	45 [1.7]	46 [2.0]
Bronchiole, Dilatation			1 [2.0]			
Serosa, Inflammation, Focal, Suppurative				1 [2.0]		
Nose	(53)	(54)	(53)	(53)	(53)	(53)
Cyst, Squamous					1 [3.0]	
Inflammation	2 [2.5]			3 [1.7]	5 [2.0]	4 [2.5]
Goblet Cell, Septum, Hyperplasia					1 [2.0]	
Nasolacrimal Duct, Inflammation	2 [2.0]					
Nasolacrimal Duct, Respiratory Epithelium, Hyperplasia					1 [2.0]	
Nasopharyngeal Duct, Inflammation				1 [3.0]		1 [4.0]
Nasopharyngeal Duct, Necrosis				1 [3.0]		
Olfactory Epithelium, Degeneration					1 [2.0]	
Olfactory Epithelium, Inflammation					1 [3.0]	1 [2.0]
Respiratory Epithelium, Cyst					2 [2.0]	
Respiratory Epithelium, Hyperplasia				1 [3.0]	2 [2.0]	
Septum, Hyperplasia, Squamous						1 [2.0]
Septum, Inflammation						2 [3.5]
Squamous Epithelium, Inflammation, Suppurative	1 [1.0]					
Turbinate, Hyperplasia, Squamous						1 [2.0]
Turbinate, Septum, Inflammation			1 [2.0]	1 [2.0]		2 [2.5]
Turbinate, Respiratory Epithelium, Hyperplasia			1 [2.0]	1 [3.0]		
SPECIAL SENSES SYSTEM						
Eye	(53)	(54)	(53)	(52)	(53)	(53)
Degeneration	1 [4.0]					
Hemorrhage	1 [2.0]					
Anterior Chamber, Inflammation, Suppurative						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)

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	3 NG/KG	10 NG/KG	22 NG/KG	46 NG/KG	100 NG/KG
SPECIAL SENSES SYSTEM - CONT						
Cornea, Inflammation, Suppurative			1 [1.0]			1 [4.0]
Lens, Degeneration					1 [4.0]	
Retina, Atrophy	5 [2.0]	5 [2.2]	5 [2.2]	3 [2.3]	4 [2.3]	6 [2.3]
Retina, Degeneration					1 [3.0]	
Harderian Gland	(53)	(54)	(53)	(52)	(53)	(53)
Atrophy, Focal	1 [2.0]					
Inflammation	12 [1.3]	3 [1.3]	2 [1.5]	2 [1.0]	8 [1.1]	6 [1.3]
URINARY SYSTEM						
Kidney	(53)	(54)	(53)	(53)	(53)	(53)
Calculus Gross Observation						1 [4.0]
Calculus Micro Observation Only	1 [2.0]	1 [0.0]	1 [0.0]	3 [0.0]	2 [2.0]	
Casts Protein	3 [1.3]	5 [1.4]	2 [1.0]		1 [1.0]	1 [1.0]
Cyst	2 [2.5]				1 [2.0]	1 [2.0]
Fibrosis		1 [2.0]				
Infarct			1 [3.0]			
Inflammation, Chronic Active	5 [1.2]	1 [1.0]		1 [2.0]	1 [2.0]	
Inflammation, Suppurative			2 [2.0]	1 [3.0]	1 [3.0]	2 [3.0]
Mineralization	40 [1.1]	39 [1.1]	30 [1.0]	32 [1.0]	42 [1.1]	42 [1.1]
Necrosis				1 [3.0]	1 [2.0]	
Nephropathy	34 [1.2]	26 [1.1]	32 [1.3]	36 [1.4]	39 [1.4]	52 [2.2]
Papilla, Necrosis			1 [3.0]			
Pelvis, Dilatation	2 [3.0]	1 [2.0]	1 [3.0]		2 [3.0]	
Pelvis, Inflammation	2 [3.0]	1 [2.0]	1 [2.0]	1 [1.0]	4 [2.3]	2 [3.0]
Renal Tubule, Degeneration						1 [2.0]
Transitional Epithelium, Hyperplasia	3 [2.3]	6 [1.7]	8 [1.8]	8 [1.3]	11 [2.0]	11 [1.8]
Ureter	(1)					
Inflammation	1 [2.0]					
Transitional Epithelium, Hyperplasia	1 [3.0]					
Urinary Bladder	(52)	(53)	(53)	(52)	(53)	(53)
Calculus Micro Observation Only		1				
Hemorrhage		1 [3.0]				
Inflammation	6 [1.5]	10 [1.3]	4 [1.5]		8 [2.0]	3 [1.7]
Metaplasia, Squamous						1 [3.0]
Transitional Epithelium, Hyperplasia	1 [2.0]	2 [2.0]	1 [2.0]		6 [2.2]	2 [2.5]

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)

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
DISPOSITION SUMMARY	
Animals Initially In Study	50
Early Deaths	
Moribund Sacrifice	16
Natural Death	13
Survivors	
Terminal Sacrifice	21
Animals Examined Microscopically	50
ALIMENTARY SYSTEM	
Intestine Large, Colon	(49)
Parasite Metazoan	1 [1.0]
Intestine Large, Rectum	(50)
Parasite Metazoan	5
Intestine Small, Jejunum	(50)
Inflammation, Chronic	1 [2.0]
Liver	(50)
Angiectasis	4 [1.5]
Atypia Cellular	1 [1.0]
Basophilic Focus	7
Basophilic Focus, Multiple	9
Cholangiofibrosis	1 [2.0]
Clear Cell Focus	6
Clear Cell Focus, Multiple	2
Cytoplasmic Alteration	1 [1.0]
Eosinophilic Focus	6
Eosinophilic Focus, Multiple	21
Fatty Change, Diffuse	10 [1.4]
Fatty Change, Focal	8 [1.3]
Hematopoietic Cell Proliferation	2 [2.5]
Hepatodiaphragmatic Nodule	1
Inflammation	43 [1.2]
Mixed Cell Focus	1
Mixed Cell Focus, Multiple	28
Necrosis	8 [1.8]
Pigmentation	45 [1.8]
Toxic Hepatopathy	16 [1.3]
Vacuolization Cytoplasmic	1 [1.0]
Bile Duct, Cyst	6 [2.3]
Bile Duct, Fibrosis	5 [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)

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
ALIMENTARY SYSTEM - CONT	
Bile Duct, Hyperplasia	7 [1.3]
Hepatocyte, Hypertrophy	22 [1.7]
Hepatocyte, Multinucleated	32 [1.3]
Oval Cell, Hyperplasia	1 [1.0]
Portal, Fibrosis	1 [2.0]
Serosa, Inflammation, Chronic Active	1 [3.0]
Mesentery	(1)
Artery, Inflammation, Chronic Active	1 [3.0]
Oral Mucosa	(11)
Gingival, Hyperplasia, Squamous	8 [1.9]
Pancreas	(49)
Angiectasis	1 [2.0]
Basophilic Focus	1 [1.0]
Inflammation, Chronic Active	4 [1.5]
Acinus, Atrophy	4 [1.8]
Artery, Inflammation, Chronic Active	2 [2.5]
Salivary Glands	(49)
Atrophy	2 [2.0]
Fibrosis	1 [2.0]
Inflammation	1 [1.0]
Stomach, Forestomach	(50)
Hyperkeratosis	1 [2.0]
Hyperplasia, Squamous	5 [1.8]
Inflammation	4 [2.0]
Ulcer	4 [2.3]
Stomach, Glandular	(50)
Erosion	1 [2.0]
Tongue	(1)
Inflammation, Chronic Active	1 [3.0]
Tooth	(12)
Peridontal Tissue, Inflammation	12 [1.6]
CARDIOVASCULAR SYSTEM	
Heart	(50)
Cardiomyopathy	22 [1.4]
Inflammation	1 [2.0]
Atrium, Thrombosis	2 [3.0]
Epicardium, 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)

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
ENDOCRINE SYSTEM	
Adrenal Cortex	(50)
Angiectasis	15 [1.9]
Atrophy	4 [1.8]
Degeneration, Cystic	17 [2.2]
Hyperplasia	20 [2.6]
Hypertrophy	46 [2.1]
Necrosis	3 [3.0]
Vacuolization Cytoplasmic	13 [1.3]
Adrenal Medulla	(50)
Hyperplasia	15 [2.1]
Islets, Pancreatic	(49)
Hyperplasia	1 [2.0]
Pituitary Gland	(50)
Angiectasis	15 [2.1]
Cytoplasmic Alteration	1 [2.0]
Vacuolization Cytoplasmic	3 [1.7]
Pars Distalis, Hyperplasia	18 [1.8]
Thyroid Gland	(49)
Angiectasis	1 [2.0]
C-Cell, Hyperplasia	15 [1.9]
Follicular Cell, Hypertrophy	6 [1.5]
GENERAL BODY SYSTEM	
None	
GENITAL SYSTEM	
Clitoral Gland	(49)
Atrophy	1 [2.0]
Hyperplasia, Basal Cell	1 [1.0]
Hyperplasia, Squamous	1 [3.0]
Inflammation	35 [1.5]
Duct, Cyst	35 [2.0]
Ovary	(49)
Atrophy	45 [4.0]
Cyst	16 [2.3]
Inflammation, Granulomatous	1 [3.0]
Oviduct	(2)
Inflammation	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)

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
GENITAL SYSTEM - CONT	
Uterus	(50)
Inflammation, Chronic Active	1 [3.0]
Inflammation, Suppurative	9 [2.7]
Metaplasia, Squamous	33 [2.1]
Cervix, Inflammation, Chronic Active	1 [3.0]
Endometrium, Hyperplasia, Cystic	32 [2.1]
HEMATOPOIETIC SYSTEM	
Bone Marrow	(50)
Atrophy	1 [2.0]
Hyperplasia	36 [2.9]
Myelofibrosis	1 [2.0]
Lymph Node	(5)
Lumbar, Ectasia	2 [2.5]
Lumbar, Hyperplasia, Plasma Cell	2 [2.5]
Mediastinal, Hemorrhage	1 [2.0]
Mediastinal, Hyperplasia, Plasma Cell	1 [2.0]
Lymph Node, Mandibular	(49)
Ectasia	2 [2.0]
Hyperplasia, Lymphoid	2 [2.5]
Hyperplasia, Plasma Cell	30 [2.2]
Lymph Node, Mesenteric	(49)
Hyperplasia, Histiocytic	1 [3.0]
Spleen	(49)
Hematopoietic Cell Proliferation	42 [1.5]
Hyperplasia, Lymphoid	1 [2.0]
Pigmentation	42 [1.6]
Lymphoid Follicle, Atrophy	1 [2.0]
Red Pulp, Atrophy	1 [2.0]
Thymus	(49)
Atrophy	45 [3.3]
INTEGUMENTARY SYSTEM	
Mammary Gland	(50)
Cyst	4 [2.3]
Hyperplasia	19 [1.2]
Skin	(50)
Ulcer	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)

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
MUSCULOSKELETAL SYSTEM	
None	
NERVOUS SYSTEM	
Brain	(50)
Hemorrhage	1 [3.0]
Inflammation, Suppurative	1 [2.0]
RESPIRATORY SYSTEM	
Lung	(50)
Infiltration Cellular, Histiocyte	41 [2.0]
Inflammation, Suppurative	1 [3.0]
Metaplasia, Squamous	3 [1.3]
Alveolar Epithelium, Metaplasia, Bronchiolar	31 [1.3]
Serosa, Inflammation, Suppurative	1 [3.0]
Nose	(50)
Inflammation	1 [1.0]
Goblet Cell, Respiratory Epithelium, Hyperplasia	1 [3.0]
Nasolacrimal Duct, Inflammation	1 [3.0]
Olfactory Epithelium, Degeneration	1 [3.0]
Olfactory Epithelium, Inflammation	1 [3.0]
Olfactory Epithelium, Glands, Hyperplasia	1 [2.0]
Respiratory Epithelium, Cyst	1 [2.0]
Respiratory Epithelium, Inflammation, Suppurative	1 [4.0]
SPECIAL SENSES SYSTEM	
Eye	(50)
Retinal Detachment	1 [3.0]
Bilateral, Cataract	1 [3.0]
Retina, Atrophy	6 [1.8]
Retina, Degeneration	1 [3.0]
Harderian Gland	(50)
Hemorrhage	1 [2.0]
Inflammation	9 [1.1]

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)

SPRAGUE-DAWLEY RATS FEMALE	100 NG/ KG/STOP
URINARY SYSTEM	
Kidney	(50)
Accumulation, Hyaline Droplet	2 [2.5]
Casts Protein	1 [1.0]
Mineralization	42 [1.0]
Nephropathy	41 [1.4]
Papilla, Transitional Epithelium, Hyperplasia	1 [1.0]
Pelvis, Dilatation	1 [2.0]
Transitional Epithelium, Hyperplasia	5 [1.4]
Urinary Bladder	(50)
Inflammation	2 [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)

END OF REPORT

National Toxicology Program

TR-526 Toxic Equivalency Factor Evaluation (Dioxin Mixture)

Revised Pathology Tables – Female Rats Core Study

- **P03 - Incidence Rates of Non-Neoplastic Lesions**
- **P05 - Incidence Rates of Neoplasms by Anatomic Site (systemic lesions abridged)**
- **P08 - Statistical Analysis of Primary Tumors**
- **P18 - Incidence Rates of Non-Neoplastic Lesions**

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
TOXIC EQUIVALENCY FACTOR EVALUATION (DIOXIN MIXTURE)

FINAL #2

Facility: Battelle Columbus Laboratory

Chemical CAS #: TEFDIOXINMIX

Lock Date: 09/12/01

Cage Range: All

Reasons For Removal: 25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

Removal Date Range: All

Treatment Groups:

Include 001	TERT.MIXCONTROL
Include 002	TERT.MIXTEQ=10
Include 003	TERT.MIXTEQ=22
Include 004	TERT.MIXTEQ=46
Include 005	TERT.MIXTEQ=100

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

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
DISPOSITION SUMMARY					
Animals Initially In Study	98	98	98	98	98
Early Deaths					
Moribund Sacrifice	26	25	22	25	33
Natural Death	11	5	6	4	10
Dosing Accident			1	1	2
Survivors					
Terminal Sacrifice	16	23	24	23	8
Animals Examined Microscopically	53	53	53	53	53
ALIMENTARY SYSTEM					
Esophagus	(53)	(53)	(53)	(53)	(53)
Muscularis, Inflammation		2 (4%)	1 (2%)	1 (2%)	
Intestine Large, Colon	(53)	(52)	(53)	(53)	(51)
Parasite Metazoan			1 (2%)		
Intestine Large, Rectum	(52)	(53)	(53)	(53)	(52)
Parasite Metazoan	2 (4%)	4 (8%)	5 (9%)	1 (2%)	
Artery, Inflammation, Chronic Active				2 (4%)	3 (6%)
Serosa, Inflammation					1 (2%)
Intestine Large, Cecum	(51)	(53)	(53)	(53)	(51)
Artery, Inflammation, Chronic Active					1 (2%)
Intestine Small, Duodenum	(52)	(53)	(53)	(53)	(52)
Serosa, Inflammation, Chronic Active					1 (2%)
Liver	(53)	(53)	(53)	(53)	(51)
Angiectasis	3 (6%)	2 (4%)			3 (6%)
Basophilic Focus	9 (17%)	14 (26%)	10 (19%)	5 (9%)	8 (16%)
Basophilic Focus, Multiple	15 (28%)	12 (23%)	3 (6%)	7 (13%)	8 (16%)
Cholangiofibrosis		2 (4%)	3 (6%)	4 (8%)	17 (33%)
Clear Cell Focus		1 (2%)	1 (2%)		
Clear Cell Focus, Multiple	1 (2%)			1 (2%)	
Degeneration, Cystic	1 (2%)			1 (2%)	2 (4%)
Eosinophilic Focus	4 (8%)	2 (4%)	5 (9%)	5 (9%)	
Eosinophilic Focus, Multiple	1 (2%)	7 (13%)	6 (11%)	15 (28%)	19 (37%)
Fatty Change, Diffuse	3 (6%)	5 (9%)	14 (26%)	34 (64%)	36 (71%)
Fatty Change, Focal	3 (6%)	4 (8%)	7 (13%)	2 (4%)	1 (2%)
Hematopoietic Cell Proliferation	16 (30%)	18 (34%)	19 (36%)	8 (15%)	9 (18%)
Hepatodiaphragmatic Nodule			1 (2%)		
Hyperplasia, Nodular		1 (2%)	3 (6%)	11 (21%)	38 (75%)
Inflammation	36 (68%)	50 (94%)	45 (85%)	50 (94%)	50 (98%)
Karyomegaly				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)
TOXIC EQUIVALENCY FACTOR EVALUATION (DIOXIN MIXTURE)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
ALIMENTARY SYSTEM - CONT					
Mixed Cell Focus	4 (8%)	5 (9%)	5 (9%)	1 (2%)	
Mixed Cell Focus, Multiple	17 (32%)	27 (51%)	30 (57%)	35 (66%)	17 (33%)
Necrosis	3 (6%)	1 (2%)	9 (17%)	3 (6%)	15 (29%)
Pigmentation	4 (8%)	35 (66%)	41 (77%)	48 (91%)	51 (100%)
Toxic Hepatopathy		5 (9%)	14 (26%)	38 (72%)	47 (92%)
Bile Duct, Cyst	1 (2%)	3 (6%)	3 (6%)	4 (8%)	9 (18%)
Bile Duct, Dilatation	1 (2%)				1 (2%)
Bile Duct, Fibrosis	3 (6%)	2 (4%)	1 (2%)	5 (9%)	1 (2%)
Bile Duct, Hyperplasia	2 (4%)	3 (6%)	5 (9%)	25 (47%)	42 (82%)
Centrilobular, Degeneration	3 (6%)	2 (4%)	1 (2%)	1 (2%)	6 (12%)
Centrilobular, Fibrosis					1 (2%)
Hepatocyte, Hypertrophy	1 (2%)	27 (51%)	34 (64%)	46 (87%)	50 (98%)
Hepatocyte, Multinucleated		12 (23%)	10 (19%)	39 (74%)	51 (100%)
Oval Cell, Hyperplasia		1 (2%)	1 (2%)	26 (49%)	42 (82%)
Portal, Fibrosis					11 (22%)
Serosa, Fibrosis					1 (2%)
Serosa, Inflammation, Chronic	1 (2%)				
Mesentery		(1)	(2)	(6)	(8)
Inflammation, Chronic Active					2 (25%)
Necrosis			1 (50%)		
Artery, Inflammation, Chronic Active		1 (100%)		3 (50%)	6 (75%)
Fat, Necrosis			1 (50%)	2 (33%)	
Oral Mucosa	(10)	(18)	(19)	(29)	(31)
Gingival, Hyperplasia, Squamous	8 (80%)	17 (94%)	18 (95%)	26 (90%)	30 (97%)
Pancreas	(52)	(53)	(53)	(53)	(51)
Degeneration	1 (2%)				
Inflammation, Chronic Active	3 (6%)	1 (2%)	6 (11%)	7 (13%)	16 (31%)
Inflammation, Granulomatous				1 (2%)	
Acinus, Atrophy	3 (6%)	2 (4%)	7 (13%)	7 (13%)	20 (39%)
Acinus, Hyperplasia	2 (4%)		1 (2%)		
Acinus, Vacuolization Cytoplasmic	1 (2%)		3 (6%)	15 (28%)	30 (59%)
Artery, Inflammation, Chronic Active		6 (11%)	3 (6%)	8 (15%)	14 (27%)
Duct, Cyst			1 (2%)		
Duct, Dilatation					5 (10%)
Duct, Inflammation, Chronic Active					2 (4%)
Salivary Glands	(53)	(53)	(53)	(53)	(53)
Atrophy	1 (2%)				
Inflammation	2 (4%)			1 (2%)	
Mineralization				1 (2%)	
Stomach, Forestomach	(53)	(53)	(53)	(53)	(52)
Cyst				1 (2%)	1 (2%)
Diverticulum				1 (2%)	
Edema	1 (2%)		1 (2%)		

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

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
ALIMENTARY SYSTEM - CONT					
Erosion			1 (2%)		
Hyperkeratosis			2 (4%)	2 (4%)	
Hyperplasia, Squamous	5 (9%)	1 (2%)	4 (8%)	9 (17%)	6 (12%)
Inflammation	2 (4%)		2 (4%)	1 (2%)	3 (6%)
Mineralization	1 (2%)		4 (8%)	2 (4%)	
Ulcer	3 (6%)		2 (4%)	1 (2%)	2 (4%)
Artery, Inflammation, Chronic Active				2 (4%)	1 (2%)
Stomach, Glandular	(53)	(53)	(53)	(53)	(52)
Erosion	1 (2%)				
Mineralization	2 (4%)	4 (8%)	3 (6%)	3 (6%)	1 (2%)
Artery, Inflammation, Chronic Active					2 (4%)
Tongue	(1)				(1)
Infiltration Cellular					1 (100%)
Tooth	(24)	(23)	(27)	(37)	(30)
Peridontal Tissue, Inflammation	23 (96%)	21 (91%)	22 (81%)	34 (92%)	30 (100%)
CARDIOVASCULAR SYSTEM					
Blood Vessel	(53)	(53)	(53)	(52)	(53)
Aorta, Mineralization				1 (2%)	3 (6%)
Heart	(53)	(53)	(53)	(52)	(53)
Cardiomyopathy	11 (21%)	26 (49%)	31 (58%)	30 (58%)	32 (60%)
Inflammation, Suppurative	1 (2%)				1 (2%)
Mineralization				1 (2%)	
Necrosis					1 (2%)
Thrombosis	1 (2%)				1 (2%)
Artery, Degeneration				1 (2%)	1 (2%)
Artery, Inflammation, Chronic Active				1 (2%)	1 (2%)
ENDOCRINE SYSTEM					
Adrenal Cortex	(52)	(53)	(53)	(53)	(51)
Angiectasis	15 (29%)	20 (38%)	18 (34%)	17 (32%)	8 (16%)
Atrophy		3 (6%)			18 (35%)
Degeneration, Cystic	9 (17%)	15 (28%)	19 (36%)	25 (47%)	16 (31%)
Hematopoietic Cell Proliferation			1 (2%)		1 (2%)
Hyperplasia	12 (23%)	26 (49%)	23 (43%)	25 (47%)	21 (41%)
Hypertrophy	44 (85%)	45 (85%)	47 (89%)	46 (87%)	45 (88%)
Inflammation				1 (2%)	
Mineralization		1 (2%)			1 (2%)
Necrosis	2 (4%)		2 (4%)		2 (4%)

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

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
ENDOCRINE SYSTEM - CONT					
Thrombosis		1 (2%)			
Vacuolization Cytoplasmic	6 (12%)	13 (25%)	11 (21%)	7 (13%)	15 (29%)
Capsule, Inflammation				1 (2%)	1 (2%)
Adrenal Medulla	(52)	(53)	(53)	(53)	(51)
Hyperplasia	10 (19%)	21 (40%)	12 (23%)	15 (28%)	9 (18%)
Islets, Pancreatic	(52)	(53)	(53)	(53)	(51)
Hyperplasia			1 (2%)	2 (4%)	
Pituitary Gland	(53)	(53)	(53)	(53)	(53)
Angiectasis	6 (11%)		1 (2%)	2 (4%)	3 (6%)
Cyst	1 (2%)		1 (2%)	2 (4%)	
Cytoplasmic Alteration		3 (6%)			
Hemorrhage	1 (2%)				
Vacuolization Cytoplasmic		1 (2%)	2 (4%)	3 (6%)	1 (2%)
Pars Distalis, Hyperplasia	18 (34%)	19 (36%)	24 (45%)	20 (38%)	19 (36%)
Pars Intermedia, Cyst			1 (2%)		
Thyroid Gland	(53)	(53)	(51)	(52)	(51)
C-Cell, Hyperplasia	24 (45%)	24 (45%)	20 (39%)	18 (35%)	14 (27%)
Follicular Cell, Hyperplasia	1 (2%)				
Follicular Cell, Hypertrophy	4 (8%)	13 (25%)	12 (24%)	18 (35%)	23 (45%)
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Clitoral Gland	(51)	(53)	(53)	(51)	(50)
Hyperplasia, Squamous				1 (2%)	
Inflammation	42 (82%)	40 (75%)	37 (70%)	33 (65%)	29 (58%)
Duct, Cyst	39 (76%)	41 (77%)	44 (83%)	39 (76%)	44 (88%)
Ovary	(52)	(52)	(53)	(53)	(51)
Atrophy	44 (85%)	44 (85%)	43 (81%)	49 (92%)	40 (78%)
Cyst	8 (15%)	16 (31%)	20 (38%)	14 (26%)	7 (14%)
Fibrosis		1 (2%)			
Hemorrhage					1 (2%)
Inflammation, Chronic Active		2 (4%)	1 (2%)	2 (4%)	5 (10%)
Artery, Inflammation, Chronic Active					1 (2%)
Oviduct		(2)		(2)	(5)
Cyst		2 (100%)			1 (20%)
Inflammation, Chronic Active				2 (100%)	4 (80%)
Uterus	(52)	(53)	(53)	(53)	(51)

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

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
GENITAL SYSTEM - CONT					
Adenomyosis		1 (2%)	1 (2%)	2 (4%)	1 (2%)
Hemorrhage	1 (2%)				1 (2%)
Inflammation, Chronic Active	1 (2%)	1 (2%)	1 (2%)	1 (2%)	3 (6%)
Inflammation, Suppurative	6 (12%)	5 (9%)	9 (17%)	13 (25%)	6 (12%)
Metaplasia, Squamous	21 (40%)	32 (60%)	32 (60%)	35 (66%)	30 (59%)
Thrombosis				1 (2%)	
Ulcer		1 (2%)		1 (2%)	
Cervix, Hyperplasia, Stromal	1 (2%)				
Endometrium, Fibrosis					1 (2%)
Endometrium, Hyperplasia, Cystic	37 (71%)	35 (66%)	34 (64%)	33 (62%)	23 (45%)
Epithelium, Necrosis	1 (2%)				
HEMATOPOIETIC SYSTEM					
Bone Marrow	(53)	(53)	(53)	(53)	(53)
Hyperplasia	36 (68%)	36 (68%)	34 (64%)	41 (77%)	48 (91%)
Lymph Node	(4)	(1)	(2)	(9)	(11)
Lumbar, Ectasia			1 (50%)		
Lumbar, Hemorrhage			1 (50%)		
Lumbar, Hyperplasia, Lymphoid			1 (50%)		1 (9%)
Lumbar, Hyperplasia, Plasma Cell	1 (25%)			3 (33%)	
Mediastinal, Ectasia		1 (100%)		4 (44%)	2 (18%)
Mediastinal, Fibrosis				1 (11%)	
Mediastinal, Hemorrhage				1 (11%)	2 (18%)
Mediastinal, Hyperplasia, Histiocytic				1 (11%)	1 (9%)
Mediastinal, Hyperplasia, Lymphoid					2 (18%)
Mediastinal, Hyperplasia, Plasma Cell					3 (27%)
Pancreatic, Ectasia	1 (25%)				
Pancreatic, Hyperplasia, Histiocytic					1 (9%)
Popliteal, Hyperplasia, Plasma Cell				1 (11%)	
Renal, Hyperplasia, Histiocytic	1 (25%)				
Lymph Node, Mandibular	(53)	(53)	(53)	(53)	(53)
Ectasia		1 (2%)	1 (2%)	2 (4%)	
Hemorrhage				1 (2%)	
Hyperplasia, Plasma Cell	31 (58%)	42 (79%)	30 (57%)	22 (42%)	27 (51%)
Necrosis, Focal				1 (2%)	
Lymph Node, Mesenteric	(52)	(53)	(53)	(53)	(50)
Ectasia	1 (2%)				
Hemorrhage	1 (2%)				1 (2%)
Hyperplasia, Histiocytic				1 (2%)	1 (2%)
Hyperplasia, Lymphoid			1 (2%)		
Pigmentation				1 (2%)	

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

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
HEMATOPOIETIC SYSTEM - CONT					
Spleen	(52)	(53)	(53)	(53)	(51)
Hematopoietic Cell Proliferation	43 (83%)	48 (91%)	42 (79%)	44 (83%)	42 (82%)
Hemorrhage					1 (2%)
Inflammation, Suppurative					1 (2%)
Necrosis	1 (2%)				1 (2%)
Pigmentation	45 (87%)	50 (94%)	52 (98%)	47 (89%)	46 (90%)
Lymphoid Follicle, Atrophy	1 (2%)	2 (4%)	3 (6%)	2 (4%)	3 (6%)
Red Pulp, Atrophy		1 (2%)	3 (6%)		
Thymus	(52)	(48)	(50)	(53)	(50)
Atrophy	32 (62%)	43 (90%)	45 (90%)	50 (94%)	48 (96%)
Cyst	2 (4%)				
Ectopic Thyroid				1 (2%)	
Hemorrhage				1 (2%)	
INTEGUMENTARY SYSTEM					
Mammary Gland	(53)	(53)	(53)	(53)	(52)
Cyst		3 (6%)	1 (2%)	1 (2%)	
Hyperplasia	22 (42%)	7 (13%)	14 (26%)	12 (23%)	9 (17%)
Inflammation, Granulomatous	3 (6%)	4 (8%)	1 (2%)	3 (6%)	1 (2%)
Inflammation, Suppurative				1 (2%)	
Skin	(53)	(53)	(53)	(53)	(53)
Cyst Epithelial Inclusion		2 (4%)	1 (2%)	3 (6%)	3 (6%)
Hyperkeratosis			1 (2%)		
Inflammation, Suppurative				1 (2%)	
Ulcer				1 (2%)	1 (2%)
Hair Follicle, Atrophy		1 (2%)			
MUSCULOSKELETAL SYSTEM					
Bone	(53)	(53)	(53)	(53)	(53)
Mineralization			1 (2%)		
NERVOUS SYSTEM					
Brain	(53)	(53)	(53)	(53)	(53)
Edema				1 (2%)	3 (6%)
Gliosis	1 (2%)				1 (2%)
Hemorrhage		1 (2%)			
Hydrocephalus	1 (2%)	4 (8%)	2 (4%)	2 (4%)	

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

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
NERVOUS SYSTEM - CONT					
Inflammation, Granulomatous			1 (2%)		
Mineralization	1 (2%)		1 (2%)	1 (2%)	
Necrosis					3 (6%)
Artery, Degeneration					1 (2%)
RESPIRATORY SYSTEM					
Lung	(53)	(53)	(53)	(53)	(53)
Congestion			1 (2%)	1 (2%)	
Cyst					1 (2%)
Edema			2 (4%)	2 (4%)	1 (2%)
Hemorrhage			1 (2%)		1 (2%)
Infiltration Cellular, Histiocyte	43 (81%)	50 (94%)	48 (91%)	48 (91%)	50 (94%)
Inflammation	4 (8%)	2 (4%)	3 (6%)	1 (2%)	2 (4%)
Metaplasia, Squamous	2 (4%)		2 (4%)	8 (15%)	11 (21%)
Mineralization				1 (2%)	
Alveolar Epithelium, Hyperplasia	21 (40%)	25 (47%)	10 (19%)	2 (4%)	2 (4%)
Alveolar Epithelium, Metaplasia, Bronchiolar		20 (38%)	33 (62%)	41 (77%)	40 (75%)
Perivascular, Inflammation, Chronic Active					1 (2%)
Nose	(53)	(53)	(53)	(53)	(53)
Inflammation	1 (2%)	2 (4%)	2 (4%)	1 (2%)	1 (2%)
Goblet Cell, Hyperplasia			2 (4%)	1 (2%)	
Goblet Cell, Septum, Hyperplasia				1 (2%)	
Nasolacrimal Duct, Inflammation				1 (2%)	
Respiratory Epithelium, Hyperplasia		1 (2%)		4 (8%)	
Turbinate, Cyst				1 (2%)	
Turbinate, Respiratory Epithelium, Hyperplasia					1 (2%)
SPECIAL SENSES SYSTEM					
Eye	(53)	(53)	(53)	(53)	(53)
Anterior Chamber, Ciliary Body, Iris, Inflammation, Suppurative					1 (2%)
Cornea, Inflammation, Suppurative					1 (2%)
Lens, Degeneration		1 (2%)			
Retina, Atrophy	1 (2%)	1 (2%)	2 (4%)	1 (2%)	3 (6%)
Harderian Gland	(53)	(53)	(52)	(53)	(53)
Inflammation	8 (15%)	11 (21%)	4 (8%)	5 (9%)	8 (15%)

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

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
URINARY SYSTEM					
Kidney	(52)	(53)	(53)	(53)	(51)
Calculus Micro Observation Only	9 (17%)	5 (9%)	8 (15%)	4 (8%)	1 (2%)
Casts Protein			1 (2%)	1 (2%)	
Cyst		1 (2%)		1 (2%)	
Developmental Malformation					1 (2%)
Fibrosis					1 (2%)
Inflammation, Chronic				1 (2%)	
Inflammation, Chronic Active	1 (2%)	1 (2%)	1 (2%)		
Inflammation, Suppurative	3 (6%)	2 (4%)	3 (6%)	3 (6%)	6 (12%)
Mineralization	41 (79%)	48 (91%)	47 (89%)	42 (79%)	35 (69%)
Nephropathy	26 (50%)	41 (77%)	40 (75%)	47 (89%)	49 (96%)
Pelvis, Dilatation	2 (4%)		1 (2%)	1 (2%)	1 (2%)
Pelvis, Inflammation	2 (4%)	1 (2%)	1 (2%)	2 (4%)	1 (2%)
Renal Tubule, Hyperplasia				2 (4%)	
Renal Tubule, Necrosis	1 (2%)		1 (2%)		
Transitional Epithelium, Hyperplasia	5 (10%)	5 (9%)	8 (15%)	10 (19%)	8 (16%)
Ureter	(1)		(1)	(1)	(1)
Cyst	1 (100%)				
Inflammation			1 (100%)		
Metaplasia, Squamous				1 (100%)	
Transitional Epithelium, Hyperplasia			1 (100%)	1 (100%)	
Urinary Bladder	(52)	(52)	(53)	(53)	(50)
Edema				1 (2%)	
Hemorrhage					1 (2%)
Inflammation	12 (23%)	3 (6%)	4 (8%)	8 (15%)	5 (10%)
Metaplasia, Squamous				1 (2%)	
Transitional Epithelium, Hyperplasia			1 (2%)	3 (6%)	4 (8%)

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

END OF REPORT

FINAL #2

Facility: Battelle Columbus Laboratory

Chemical CAS #: TEFDIOXINMIX

Lock Date: 09/12/01

Cage Range: All

Reasons For Removal: 25018 Dosing Accident 25019 Moribund Sacrifice
25020 Natural Death 25021 Terminal Sacrifice

Removal Date Range: All

Treatment Groups:

Include 001	TERT.MIXCONTROL
Include 002	TERT.MIXTEQ=10
Include 003	TERT.MIXTEQ=22
Include 004	TERT.MIXTEQ=46
Include 005	TERT.MIXTEQ=100

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

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
DISPOSITION SUMMARY					
Animals Initially in Study	98	98	98	98	98
Early Deaths					
Moribund Sacrifice	26	25	22	25	33
Natural Death	11	5	6	4	10
Dosing Accident			1	1	2
Survivors					
Terminal Sacrifice	16	23	24	23	8
Animals Examined Microscopically	53	53	53	53	53
ALIMENTARY SYSTEM					
Intestine Large, Colon	(53)	(52)	(53)	(53)	(51)
Carcinoma	1 (2%)				
Intestine Large, Rectum	(52)	(53)	(53)	(53)	(52)
Polyp Adenomatous			1 (2%)		
Schwannoma Malignant, Metastatic, Uterus				1 (2%)	
Intestine Large, Cecum	(51)	(53)	(53)	(53)	(51)
Intestine Small, Duodenum	(52)	(53)	(53)	(53)	(52)
Carcinoma			1 (2%)		
Intestine Small, Jejunum	(52)	(53)	(53)	(53)	(50)
Leiomyosarcoma	1 (2%)		1 (2%)		
Intestine Small, Ileum	(52)	(53)	(53)	(53)	(50)
Liver	(53)	(53)	(53)	(53)	(51)
Cholangiocarcinoma			2 (4%)	5 (9%)	5 (10%)
Cholangiocarcinoma, Multiple				2 (4%)	4 (8%)
Hepatocellular Adenoma		1 (2%)			
Histiocytic Sarcoma					1 (2%)
Mesentery		(1)	(2)	(6)	(8)
Histiocytic Sarcoma					1 (13%)
Lipoma				1 (17%)	
Oral Mucosa	(10)	(18)	(19)	(29)	(31)
Gingival, Squamous Cell Carcinoma	1 (10%)	1 (6%)			2 (6%)
Pancreas	(52)	(53)	(53)	(53)	(51)
Acinus, Adenoma			2 (4%)		
Acinus, Carcinoma		1 (2%)		2 (4%)	
Salivary Glands	(53)	(53)	(53)	(53)	(53)
Carcinoma		1 (2%)			
Schwannoma Malignant, Metastatic, Skin					1 (2%)
Stomach, Forestomach	(53)	(53)	(53)	(53)	(52)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
ALIMENTARY SYSTEM - cont					
Stomach, Glandular	(53)	(53)	(53)	(53)	(52)
Tongue	(1)				(1)
Squamous Cell Carcinoma, Metastatic, Oral Mucosa	1 (100%)				
Tooth	(24)	(23)	(27)	(37)	(30)
Peridontal Tissue, Fibrosarcoma	1 (4%)				
CARDIOVASCULAR SYSTEM					
Blood Vessel	(53)	(53)	(53)	(52)	(53)
Aorta, Adventitia, Carcinoma, Metastatic, Mammary Gland	1 (2%)				
Heart	(53)	(53)	(53)	(52)	(53)
Fibrous Histiocytoma, Metastatic, Skeletal Muscle		1 (2%)			
Schwannoma Malignant	2 (4%)			1 (2%)	3 (6%)
ENDOCRINE SYSTEM					
Adrenal Cortex	(52)	(53)	(53)	(53)	(51)
Adenoma		1 (2%)	1 (2%)		
Carcinoma		1 (2%)	1 (2%)		
Adrenal Medulla	(52)	(53)	(53)	(53)	(51)
Pheochromocytoma Benign	4 (8%)	3 (6%)	4 (8%)	4 (8%)	1 (2%)
Bilateral, Pheochromocytoma Benign	1 (2%)	1 (2%)			
Islets, Pancreatic	(52)	(53)	(53)	(53)	(51)
Adenoma	1 (2%)	1 (2%)	1 (2%)	1 (2%)	
Carcinoma	1 (2%)				
Parathyroid Gland	(50)	(50)	(49)	(47)	(52)
Adenoma	1 (2%)				
Pituitary Gland	(53)	(53)	(53)	(53)	(53)
Carcinoma			1 (2%)		
Pars Distalis, Adenoma	28 (53%)	29 (55%)	22 (42%)	20 (38%)	10 (19%)
Thyroid Gland	(53)	(53)	(51)	(52)	(51)
Bilateral, C-Cell, Adenoma	2 (4%)	2 (4%)	3 (6%)	1 (2%)	
Bilateral, Follicular Cell, Carcinoma			1 (2%)		
C-Cell, Adenoma	15 (28%)	8 (15%)	15 (29%)	8 (15%)	5 (10%)
C-Cell, Carcinoma	2 (4%)			1 (2%)	1 (2%)
Follicular Cell, Adenoma			1 (2%)		1 (2%)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Ovary	(52)	(52)	(53)	(53)	(51)
Fibrous Histiocytoma, Metastatic, Skeletal Muscle		1 (2%)			
Granulosa Cell Tumor Malignant			1 (2%)		1 (2%)
Granulosa Cell Tumor Benign			1 (2%)	1 (2%)	
Uterus	(52)	(53)	(53)	(53)	(51)
Carcinoma		1 (2%)	2 (4%)	2 (4%)	1 (2%)
Hemangiosarcoma					1 (2%)
Histiocytic Sarcoma					1 (2%)
Leiomyoma			2 (4%)		
Leiomyosarcoma	1 (2%)				
Polyp Stromal	3 (6%)	1 (2%)	2 (4%)	3 (6%)	2 (4%)
Polyp Stromal, Multiple	1 (2%)		1 (2%)		
Schwannoma Malignant	1 (2%)		1 (2%)	2 (4%)	1 (2%)
Squamous Cell Carcinoma			1 (2%)		
Squamous Cell Papilloma	1 (2%)				
Cervix, Carcinoma	1 (2%)				
Cervix, Squamous Cell Carcinoma		1 (2%)			1 (2%)
Serosa, Carcinoma, Metastatic, Uterus	1 (2%)				
Vagina				(1)	
Schwannoma Malignant				1 (100%)	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(53)	(53)	(53)	(53)	(53)
Lymph Node	(4)	(1)	(2)	(9)	(11)
Deep Cervical, Carcinoma, Metastatic, Thyroid Gland				1 (11%)	
Pancreatic, Histiocytic Sarcoma					1 (9%)
Renal, Histiocytic Sarcoma					1 (9%)
Lymph Node, Mandibular	(53)	(53)	(53)	(53)	(53)
Lymph Node, Mesenteric	(52)	(53)	(53)	(53)	(50)
Histiocytic Sarcoma					1 (2%)
Spleen	(52)	(53)	(53)	(53)	(51)
Thymus	(52)	(48)	(50)	(53)	(50)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
HEMATOPOIETIC SYSTEM - cont					
Fibrosarcoma, Metastatic, Skin	1 (2%)				
INTEGUMENTARY SYSTEM					
Mammary Gland	(53)	(53)	(53)	(53)	(52)
Adenoacanthoma			1 (2%)		
Adenolipoma			1 (2%)		
Adenoma		1 (2%)			
Carcinoma	5 (9%)	6 (11%)	3 (6%)	5 (9%)	1 (2%)
Carcinoma, Multiple	1 (2%)				
Fibroadenoma	21 (40%)	17 (32%)	19 (36%)	20 (38%)	15 (29%)
Fibroadenoma, Multiple	13 (25%)	10 (19%)	16 (30%)	8 (15%)	3 (6%)
Skin	(53)	(53)	(53)	(53)	(53)
Fibroma	1 (2%)	2 (4%)	2 (4%)	3 (6%)	
Fibrosarcoma	1 (2%)			1 (2%)	
Pilomatrixoma				1 (2%)	
Schwannoma Malignant					1 (2%)
Schwannoma Malignant, Metastatic, Uterus				1 (2%)	
Squamous Cell Papilloma			1 (2%)		
MUSCULOSKELETAL SYSTEM					
Skeletal Muscle		(1)			
Fibrous Histiocytoma		1 (100%)			
NERVOUS SYSTEM					
Brain	(53)	(53)	(53)	(53)	(53)
Carcinoma, Metastatic, Kidney	1 (2%)				
Carcinoma, Metastatic, Pituitary Gland			1 (2%)		
Granular Cell Tumor Malignant			1 (2%)		
Medulloblastoma Mal		1 (2%)	1 (2%)		
Oligodendroglioma Malignant			1 (2%)		
Meninges, Meningioma Malignant		1 (2%)			
Spinal Cord	(1)	(1)			

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
RESPIRATORY SYSTEM					
Lung	(53)	(53)	(53)	(53)	(53)
Alveolar/Bronchiolar Adenoma			1 (2%)	1 (2%)	
Carcinoma, Metastatic, Mammary Gland	3 (6%)	1 (2%)		2 (4%)	
Carcinoma, Metastatic, Uterus	1 (2%)				
Carcinoma, Metastatic, Adrenal Cortex			1 (2%)		
Cystic Keratinizing Epithelioma				2 (4%)	9 (17%)
Cystic Keratinizing Epithelioma, Multiple					11 (21%)
Fibrosarcoma, Metastatic, Skin	1 (2%)				
Fibrous Histiocytoma, Metastatic, Skeletal Muscle		1 (2%)			
Histiocytic Sarcoma					1 (2%)
Schwannoma Malignant, Metastatic, Skin					1 (2%)
Mediastinum, Carcinoma, Metastatic, Mammary Gland	1 (2%)				
Mediastinum, Fibrous Histiocytoma, Metastatic, Skeletal Muscle		1 (2%)			
Nose	(53)	(53)	(53)	(53)	(53)
Schwannoma Malignant			1 (2%)		
SPECIAL SENSES SYSTEM					
Harderian Gland	(53)	(53)	(52)	(53)	(53)
Histiocytic Sarcoma					1 (2%)
URINARY SYSTEM					
Kidney	(52)	(53)	(53)	(53)	(51)
Hemangiosarcoma			1 (2%)		
Nephroblastoma	1 (2%)				
Bilateral, Renal Tubule, Carcinoma	1 (2%)				
Renal Tubule, Carcinoma		1 (2%)			
Transitional Epithelium, Papilloma				1 (2%)	
SYSTEMIC LESIONS					
Multiple Organs	*(53)	*(53)	*(53)	*(53)	*(53)
Adenolipoma			1 (2%)		

* Number of animals with any tissue examined microscopically

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
SYSTEMIC LESIONS - cont					
Multiple Organs	*(53)	*(53)	*(53)	*(53)	*(53)
Histiocytic Sarcoma					4 (8%)
Lymphoma Malignant	2 (4%)	1 (2%)		1 (2%)	1 (2%)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
TUMOR SUMMARY					
Total Animals with Primary Neoplasms (b)	51	46	50	50	45
Total Primary Neoplasms	115	94	117	98	84
Total Animals with Benign Neoplasms	45	43	46	43	36
Total Benign Neoplasms	92	77	96	74	57
Total Animals with Malignant Neoplasms	18	14	19	21	23
Total Malignant Neoplasms	23	17	21	23	27
Total Animals with Metastatic Neoplasms	7	2	2	4	1
Total Metastatic Neoplasm	11	5	2	5	2
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 #2

REASONS FOR REMOVAL:
25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:

INCLUDE	001	TERT.MIXCONTROL
INCLUDE	002	TERT.MIXTEQ=10
INCLUDE	003	TERT.MIXTEQ=22
INCLUDE	004	TERT.MIXTEQ=46
INCLUDE	005	TERT.MIXTEQ=100

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 04
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD
Rats(SPRAGUE-DAWLEY)

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (DIOXIN MIXTURE)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/23/03
TIME: 12:17:36

NTP C#: 96007B
CAS: TEFDIOXINMIX

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
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Nose
Ovary
Pancreas
Parathyroid Gland
Pituitary Gland
Salivary Glands
Thyroid Gland

NTP
LAB: Battelle Columbus
EXPERIMENT: 96007 TEST: 04
TEST TYPE: CHRONIC
CONT: NO1-ES-75411
PATHOLOGIST: SELLS, DONALD

STATISTICAL ANALYSIS OF PRIMARY TUMORS
TOXIC EQUIVALENCY FACTOR EVALUATION (DIOXIN MIXTURE)

CAGES FROM 0000 TO LAST CAGE
ROUTE: GAVAGE

REPORT: PEIRPT08
DATE: 08/23/03
TIME: 12:17:36

NTP C#: 96007B
CAS: TEFDIOXINMIX

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX

Female Rats

Organ	Morphology
Liver	Cholangiocarcinoma
Lung	Cystic Keratinizing Epithelioma
Mammary Gland	Carcinoma
	Carcinoma or Adenoma
	Fibroadenoma
	Fibroma, Fibroadenoma or Adenoma
	Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Pituitary Gland: Pars Distalis or Unspecified Site	Adenoma
	Carcinoma or Adenoma
Thyroid Gland: C-Cell	Adenoma
	Carcinoma or Adenoma
All Organs	Histiocytic Sarcoma
	Benign Tumors
	Malignant Tumors
	Malignant and Benign Tumors

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

	Females				
Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Adrenal Medulla					
Pheochromocytoma Benign					
TUMOR RATES					
OVERALL (a)	5/52 (10%)	4/53 (8%)	4/53 (8%)	4/53 (8%)	1/51 (2%)
POLY-3 RATE (b)	5/35.98	4/41.21	4/42.32	4/39.85	1/32.48
POLY-3 PERCENT (g)	13.9%	9.7%	9.5%	10.0%	3.1%
TERMINAL (d)	3/16 (19%)	1/23 (4%)	1/24 (4%)	2/23 (9%)	0/8 (0%)
FIRST INCIDENCE	693	456	456	669	674
STATISTICAL TESTS					
LIFE TABLE	P=0.207N	P=0.345N	P=0.305N	P=0.333N	P=0.263N
POLY 3	P=0.128N	P=0.414N	P=0.398N	P=0.435N	P=0.122N
POLY 1.5	P=0.107N	P=0.441N	P=0.437N	P=0.454N	P=0.112N
POLY 6	P=0.161N	P=0.383N	P=0.356N	P=0.411N	P=0.143N
LOGISTIC REGRESSION	P=0.109N	P=0.435N	P=0.414N	P=0.403N	P=0.180N
COCH-ARM / FISHERS	P=0.089N	P=0.488N	P=0.488N	P=0.488N	P=0.107N
ORDER RESTRICTED	P=0.118N	(e)	(e)	(e)	(e)

	Females				
Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Heart					
Schwannoma Malignant					
TUMOR RATES					
OVERALL (a)	2/53 (4%)	0/53 (0%)	0/53 (0%)	1/52 (2%)	3/53 (6%)
POLY-3 RATE (b)	2/36.88	0/39.99	0/41.29	1/40.10	3/34.73
POLY-3 PERCENT (g)	5.4%	0.0%	0.0%	2.5%	8.6%
TERMINAL (d)	1/16 (6%)	0/23 (0%)	0/24 (0%)	0/23 (0%)	0/8 (0%)
FIRST INCIDENCE	526	---	---	465	312
STATISTICAL TESTS					
LIFE TABLE	P=0.080	P=0.189N	P=0.180N	P=0.441N	P=0.434
POLY 3	P=0.090	P=0.219N	P=0.212N	P=0.471N	P=0.472
POLY 1.5	P=0.098	P=0.225N	P=0.223N	P=0.483N	P=0.486
POLY 6	P=0.081	P=0.212N	P=0.201N	P=0.458N	P=0.446
LOGISTIC REGRESSION	P=0.166	P=0.237N	P=0.237N	P=0.546N	P=0.553
COCH-ARM / FISHERS	P=0.111	P=0.248N	P=0.248N	P=0.507N	P=0.500
ORDER RESTRICTED	P=0.077	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	Females TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Islets, Pancreatic Carcinoma or Adenoma					
TUMOR RATES					
OVERALL (a)	2/52 (4%)	1/53 (2%)	1/53 (2%)	1/53 (2%)	0/51 (0%)
POLY-3 RATE (b)	2/36.05	1/39.99	1/41.29	1/39.44	0/32.27
POLY-3 PERCENT (g)	5.6%	2.5%	2.4%	2.5%	0.0%
TERMINAL (d)	1/16 (6%)	1/23 (4%)	1/24 (4%)	1/23 (4%)	0/8 (0%)
FIRST INCIDENCE	655	729 (T)	729 (T)	729 (T)	---
STATISTICAL TESTS					
LIFE TABLE	P=0.270N	P=0.402N	P=0.383N	P=0.395N	P=0.348N
POLY 3	P=0.207N	P=0.464N	P=0.453N	P=0.469N	P=0.261N
POLY 1.5	P=0.195N	P=0.473N	P=0.470N	P=0.477N	P=0.249N
POLY 6	P=0.222N	P=0.454N	P=0.435N	P=0.460N	P=0.284N
LOGISTIC REGRESSION	P=0.231N	P=0.445N	P=0.427N	P=0.452N	P=0.280N
COCH-ARM / FISHERS	P=0.182N	P=0.493N	P=0.493N	P=0.493N	P=0.252N
ORDER RESTRICTED	P=0.143N	(e)	(e)	(e)	(e)

Dose	Females TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Liver Cholangiocarcinoma					
TUMOR RATES					
OVERALL (a)	0/53 (0%)	0/53 (0%)	2/53 (4%)	7/53 (13%)	9/51 (18%)
POLY-3 RATE (b)	0/36.25	0/39.99	2/41.51	7/40.30	9/34.61
POLY-3 PERCENT (g)	0.0%	0.0%	4.8%	17.4%	26.0%
TERMINAL (d)	0/16 (0%)	0/23 (0%)	1/24 (4%)	5/23 (22%)	1/8 (13%)
FIRST INCIDENCE	---	---	669	521	548
STATISTICAL TESTS					
LIFE TABLE	P<0.001 **	(e)	P=0.321	P=0.025 *	P<0.001 **
POLY 3	P<0.001 **	(e)	P=0.268	P=0.011 *	P<0.001 **
POLY 1.5	P<0.001 **	(e)	P=0.254	P=0.009 **	P<0.001 **
POLY 6	P<0.001 **	(e)	P=0.285	P=0.012 *	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	(e)	P=0.276	P=0.013 *	P=0.002 **
COCH-ARM / FISHERS	P<0.001 **	(e)	P=0.248	P=0.006 **	P<0.001 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	Females TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Lung Cystic Keratinizing Epithelioma					
TUMOR RATES					
OVERALL (a)	0/53 (0%)	0/53 (0%)	0/53 (0%)	2/53 (4%)	20/53 (38%)
POLY-3 RATE (b)	0/36.25	0/39.99	0/41.29	2/39.57	20/36.59
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	5.1%	54.7%
TERMINAL (d)	0/16 (0%)	0/23 (0%)	0/24 (0%)	1/23 (4%)	5/8 (63%)
FIRST INCIDENCE	---	---	---	697	542
STATISTICAL TESTS					
LIFE TABLE	P<0.001 **	(e)	(e)	P=0.300	P<0.001 **
POLY 3	P<0.001 **	(e)	(e)	P=0.256	P<0.001 **
POLY 1.5	P<0.001 **	(e)	(e)	P=0.249	P<0.001 **
POLY 6	P<0.001 **	(e)	(e)	P=0.266	P<0.001 **
LOGISTIC REGRESSION	P<0.001 **	(e)	(e)	P=0.271	P<0.001 **
COCH-ARM / FISHERS	P<0.001 **	(e)	(e)	P=0.248	P<0.001 **
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)

Dose	Females TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Mammary Gland Carcinoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	6/53 (11%)	6/53 (11%)	3/53 (6%)	5/53 (9%)	1/53 (2%)
POLY-3 RATE (b)	6/38.75	6/42.31	3/41.42	5/41.78	1/32.91
POLY-3 PERCENT (g)	15.5%	14.2%	7.2%	12.0%	3.0%
TERMINAL (d)	2/16 (13%)	3/23 (13%)	1/24 (4%)	2/23 (9%)	0/8 (0%)
FIRST INCIDENCE	218	227	702	276	548
STATISTICAL TESTS					
LIFE TABLE	P=0.111N	P=0.481N	P=0.137N	P=0.388N	P=0.120N
POLY 3	P=0.081N	P=0.559N	P=0.207N	P=0.446N	P=0.084N
POLY 1.5	P=0.065N	P=0.579N	P=0.225N	P=0.465N	P=0.072N
POLY 6	P=0.105N	P=0.535N	P=0.187N	P=0.426N	P=0.105N
LOGISTIC REGRESSION	P=0.033N*	P=0.535	P=0.254N	P=0.584N	P=0.049N*
COCH-ARM / FISHERS	P=0.046N*	P=0.620N	P=0.244N	P=0.500N	P=0.056N
ORDER RESTRICTED	P=0.080N	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Mammary Gland Carcinoma or Adenoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	6/53 (11%)	7/53 (13%)	3/53 (6%)	5/53 (9%)	1/53 (2%)
POLY-3 RATE (b)	6/38.75	7/42.36	3/41.42	5/41.78	1/32.91
POLY-3 PERCENT (g)	15.5%	16.5%	7.2%	12.0%	3.0%
TERMINAL (d)	2/16 (13%)	3/23 (13%)	1/24 (4%)	2/23 (9%)	0/8 (0%)
FIRST INCIDENCE	218	227	702	276	548
STATISTICAL TESTS					
LIFE TABLE	P=0.092N	P=0.579N	P=0.137N	P=0.388N	P=0.120N
POLY 3	P=0.062N	P=0.570	P=0.207N	P=0.446N	P=0.084N
POLY 1.5	P=0.050N	P=0.546	P=0.225N	P=0.465N	P=0.072N
POLY 6	P=0.082N	P=0.597	P=0.187N	P=0.426N	P=0.105N
LOGISTIC REGRESSION	P=0.026N*	P=0.423	P=0.254N	P=0.584N	P=0.049N*
COCH-ARM / FISHERS	P=0.035N*	P=0.500	P=0.244N	P=0.500N	P=0.056N
ORDER RESTRICTED	P=0.072N	(e)	(e)	(e)	(e)

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Mammary Gland Fibroadenoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	34/53 (64%)	27/53 (51%)	35/53 (66%)	28/53 (53%)	18/53 (34%)
POLY-3 RATE (b)	34/45.66	27/47.68	35/48.71	28/45.80	18/36.95
POLY-3 PERCENT (g)	74.5%	56.6%	71.9%	61.1%	48.7%
TERMINAL (d)	11/16 (69%)	8/23 (35%)	16/24 (67%)	10/23 (44%)	6/8 (75%)
FIRST INCIDENCE	176	362	263	333	409
STATISTICAL TESTS					
LIFE TABLE	P=0.258N	P=0.041N*	P=0.145N	P=0.047N*	P=0.183N
POLY 3	P=0.024N*	P=0.047N*	P=0.477N	P=0.115N	P=0.008N**
POLY 1.5	P=0.006N**	P=0.067N	P=0.565N	P=0.129N	P=0.003N**
POLY 6	P=0.089N	P=0.033N*	P=0.400N	P=0.100N	P=0.031N*
LOGISTIC REGRESSION	P=0.002N**	P=0.107N	P=0.561	P=0.126N	P=0.003N**
COCH-ARM / FISHERS	P<0.001N**	P=0.119N	P=0.500	P=0.162N	P=0.002N**
ORDER RESTRICTED	P=0.011N*	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Mammary Gland Fibroma, Fibroadenoma or Adenoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	34/53 (64%)	28/53 (53%)	35/53 (66%)	28/53 (53%)	18/53 (34%)
POLY-3 RATE (b)	34/45.66	28/47.72	35/48.71	28/45.80	18/36.95
POLY-3 PERCENT (g)	74.5%	58.7%	71.9%	61.1%	48.7%
TERMINAL (d)	11/16 (69%)	8/23 (35%)	16/24 (67%)	10/23 (44%)	6/8 (75%)
FIRST INCIDENCE	176	362	263	333	409
STATISTICAL TESTS					
LIFE TABLE	P=0.241N	P=0.055N	P=0.145N	P=0.047N*	P=0.183N
POLY 3	P=0.018N*	P=0.072N	P=0.477N	P=0.115N	P=0.008N**
POLY 1.5	P=0.005N**	P=0.098N	P=0.565N	P=0.129N	P=0.003N**
POLY 6	P=0.074N	P=0.051N	P=0.400N	P=0.100N	P=0.031N*
LOGISTIC REGRESSION	P=0.002N**	P=0.143N	P=0.561	P=0.126N	P=0.003N**
COCH-ARM / FISHERS	P<0.001N**	P=0.162N	P=0.500	P=0.162N	P=0.002N**
ORDER RESTRICTED	P=0.011N*	(e)	(e)	(e)	(e)

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Mammary Gland Fibroma, Fibroadenoma, Carcinoma, or Adenoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	37/53 (70%)	33/53 (62%)	36/53 (68%)	31/53 (58%)	19/53 (36%)
POLY-3 RATE (b)	37/48.01	33/50.04	36/48.82	31/48.14	19/37.52
POLY-3 PERCENT (g)	77.1%	65.9%	73.7%	64.4%	50.6%
TERMINAL (d)	11/16 (69%)	10/23 (44%)	16/24 (67%)	10/23 (44%)	6/8 (75%)
FIRST INCIDENCE	176	227	263	276	409
STATISTICAL TESTS					
LIFE TABLE	P=0.156N	P=0.093N	P=0.092N	P=0.055N	P=0.123N
POLY 3	P=0.008N**	P=0.151N	P=0.441N	P=0.116N	P=0.005N**
POLY 1.5	P<0.001N**	P=0.188N	P=0.490N	P=0.128N	P=0.002N**
POLY 6	P=0.042N*	P=0.118N	P=0.394N	P=0.104N	P=0.026N*
LOGISTIC REGRESSION	P<0.001N**	P=0.316N	P=0.475N	P=0.168N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.269N	P=0.500N	P=0.156N	P<0.001N**
ORDER RESTRICTED	P=0.007N**	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	1/53 (2%)	1/53 (2%)	0/53 (0%)	0/53 (0%)	2/53 (4%)
POLY-3 RATE (b)	1/36.48	1/40.53	0/41.29	0/39.44	2/33.59
POLY-3 PERCENT (g)	2.7%	2.5%	0.0%	0.0%	6.0%
TERMINAL (d)	0/16 (0%)	0/23 (0%)	0/24 (0%)	0/23 (0%)	0/8 (0%)
FIRST INCIDENCE	668	563	---	---	434
STATISTICAL TESTS					
LIFE TABLE	P=0.232	P=0.730N	P=0.454N	P=0.443N	P=0.450
POLY 3	P=0.261	P=0.737N	P=0.475N	P=0.484N	P=0.471
POLY 1.5	P=0.270	P=0.746N	P=0.486N	P=0.490N	P=0.484
POLY 6	P=0.251	P=0.727N	P=0.464N	P=0.478N	P=0.449
LOGISTIC REGRESSION	P=0.318	P=0.758	P=0.485N	P=0.488N	P=0.516
COCH-ARM / FISHERS	P=0.283	P=0.752N	P=0.500N	P=0.500N	P=0.500
ORDER RESTRICTED	P=0.155	(e)	(e)	(e)	(e)

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	1/53 (2%)	1/53 (2%)	0/53 (0%)	0/53 (0%)	2/53 (4%)
POLY-3 RATE (b)	1/36.48	1/40.53	0/41.29	0/39.44	2/33.59
POLY-3 PERCENT (g)	2.7%	2.5%	0.0%	0.0%	6.0%
TERMINAL (d)	0/16 (0%)	0/23 (0%)	0/24 (0%)	0/23 (0%)	0/8 (0%)
FIRST INCIDENCE	668	563	---	---	434
STATISTICAL TESTS					
LIFE TABLE	P=0.232	P=0.730N	P=0.454N	P=0.443N	P=0.450
POLY 3	P=0.261	P=0.737N	P=0.475N	P=0.484N	P=0.471
POLY 1.5	P=0.270	P=0.746N	P=0.486N	P=0.490N	P=0.484
POLY 6	P=0.251	P=0.727N	P=0.464N	P=0.478N	P=0.449
LOGISTIC REGRESSION	P=0.318	P=0.758	P=0.485N	P=0.488N	P=0.516
COCH-ARM / FISHERS	P=0.283	P=0.752N	P=0.500N	P=0.500N	P=0.500
ORDER RESTRICTED	P=0.155	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	Females TERT.MIX CONTROL	 TERT.MIX TEQ=10	 TERT.MIX TEQ=22	 TERT.MIX TEQ=46	 TERT.MIX TEQ=100
Oral Mucosa Squamous Cell Carcinoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	1/53 (2%)	1/53 (2%)	0/53 (0%)	0/53 (0%)	2/53 (4%)
POLY-3 RATE (b)	1/36.48	1/40.53	0/41.29	0/39.44	2/33.59
POLY-3 PERCENT (g)	2.7%	2.5%	0.0%	0.0%	6.0%
TERMINAL (d)	0/16 (0%)	0/23 (0%)	0/24 (0%)	0/23 (0%)	0/8 (0%)
FIRST INCIDENCE	668	563	---	---	434
STATISTICAL TESTS					
LIFE TABLE	P=0.232	P=0.730N	P=0.454N	P=0.443N	P=0.450
POLY 3	P=0.261	P=0.737N	P=0.475N	P=0.484N	P=0.471
POLY 1.5	P=0.270	P=0.746N	P=0.486N	P=0.490N	P=0.484
POLY 6	P=0.251	P=0.727N	P=0.464N	P=0.478N	P=0.449
LOGISTIC REGRESSION	P=0.318	P=0.758	P=0.485N	P=0.488N	P=0.516
COCH-ARM / FISHERS	P=0.283	P=0.752N	P=0.500N	P=0.500N	P=0.500
ORDER RESTRICTED	P=0.155	(e)	(e)	(e)	(e)

Dose	Females TERT.MIX CONTROL	 TERT.MIX TEQ=10	 TERT.MIX TEQ=22	 TERT.MIX TEQ=46	 TERT.MIX TEQ=100
Ovary Granulosa Cell Tumor: Benign, Malignant, NOS					
TUMOR RATES					
OVERALL (a)	0/52 (0%)	0/52 (0%)	2/53 (4%)	1/53 (2%)	1/51 (2%)
POLY-3 RATE (b)	0/35.78	0/39.75	2/41.67	1/39.44	1/32.46
POLY-3 PERCENT (g)	0.0%	0.0%	4.8%	2.5%	3.1%
TERMINAL (d)	0/16 (0%)	0/23 (0%)	1/24 (4%)	1/23 (4%)	0/8 (0%)
FIRST INCIDENCE	---	---	621	729 (T)	682
STATISTICAL TESTS					
LIFE TABLE	P=0.229	(e)	P=0.297	P=0.572	P=0.443
POLY 3	P=0.327	(e)	P=0.272	P=0.519	P=0.481
POLY 1.5	P=0.354	(e)	P=0.258	P=0.514	P=0.490
POLY 6	P=0.289	(e)	P=0.288	P=0.526	P=0.465
LOGISTIC REGRESSION	P=0.322	(e)	P=0.260	P=0.572	P=0.468
COCH-ARM / FISHERS	P=0.379	(e)	P=0.252	P=0.505	P=0.495
ORDER RESTRICTED	P=0.291	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	Females TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Pancreas Adenoma					
TUMOR RATES					
OVERALL (a)	0/52 (0%)	0/53 (0%)	2/53 (4%)	0/53 (0%)	0/51 (0%)
POLY-3 RATE (b)	0/35.78	0/39.99	2/41.29	0/39.44	0/32.27
POLY-3 PERCENT (g)	0.0%	0.0%	4.8%	0.0%	0.0%
TERMINAL (d)	0/16 (0%)	0/23 (0%)	2/24 (8%)	0/23 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	729 (T)	---	---
STATISTICAL TESTS					
LIFE TABLE	P=0.656N	(e)	P=0.330	(e)	(e)
POLY 3	P=0.506N	(e)	P=0.270	(e)	(e)
POLY 1.5	P=0.504N	(e)	P=0.257	(e)	(e)
POLY 6	P=0.509N	(e)	P=0.284	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.330	(e)	(e)
COCH-ARM / FISHERS	P=0.504N	(e)	P=0.252	(e)	(e)
ORDER RESTRICTED	P=0.432	(e)	(e)	(e)	(e)

Dose	Females TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Pancreas Carcinoma					
TUMOR RATES					
OVERALL (a)	0/52 (0%)	1/53 (2%)	0/53 (0%)	2/53 (4%)	0/51 (0%)
POLY-3 RATE (b)	0/35.78	1/39.99	0/41.29	2/39.44	0/32.27
POLY-3 PERCENT (g)	0.0%	2.5%	0.0%	5.1%	0.0%
TERMINAL (d)	0/16 (0%)	1/23 (4%)	0/24 (0%)	2/23 (9%)	0/8 (0%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)	---
STATISTICAL TESTS					
LIFE TABLE	P=0.573	P=0.572	(e)	P=0.320	(e)
POLY 3	P=0.623	P=0.522	(e)	P=0.259	(e)
POLY 1.5	P=0.662	P=0.516	(e)	P=0.253	(e)
POLY 6	P=0.560	P=0.529	(e)	P=0.266	(e)
LOGISTIC REGRESSION	(e)	P=0.572	(e)	P=0.320	(e)
COCH-ARM / FISHERS	P=0.648N	P=0.505	(e)	P=0.252	(e)
ORDER RESTRICTED	P=0.333	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	Females TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Pancreas Carcinoma or Adenoma					
TUMOR RATES					
OVERALL (a)	0/52 (0%)	1/53 (2%)	2/53 (4%)	2/53 (4%)	0/51 (0%)
POLY-3 RATE (b)	0/35.78	1/39.99	2/41.29	2/39.44	0/32.27
POLY-3 PERCENT (g)	0.0%	2.5%	4.8%	5.1%	0.0%
TERMINAL (d)	0/16 (0%)	1/23 (4%)	2/24 (8%)	2/23 (9%)	0/8 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)	---
STATISTICAL TESTS					
LIFE TABLE	P=0.633	P=0.572	P=0.330	P=0.320	(e)
POLY 3	P=0.533N	P=0.522	P=0.270	P=0.259	(e)
POLY 1.5	P=0.506N	P=0.516	P=0.257	P=0.253	(e)
POLY 6	P=0.574N	P=0.529	P=0.284	P=0.266	(e)
LOGISTIC REGRESSION	(e)	P=0.572	P=0.330	P=0.320	(e)
COCH-ARM / FISHERS	P=0.483N	P=0.505	P=0.252	P=0.252	(e)
ORDER RESTRICTED	P=0.338	(e)	(e)	(e)	(e)

Dose	Females TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma					
TUMOR RATES					
OVERALL (a)	28/53 (53%)	29/53 (55%)	22/53 (42%)	20/53 (38%)	10/53 (19%)
POLY-3 RATE (b)	28/41.67	29/46.41	22/43.67	20/41.29	10/33.29
POLY-3 PERCENT (g)	67.2%	62.5%	50.4%	48.4%	30.0%
TERMINAL (d)	11/16 (69%)	11/23 (48%)	12/24 (50%)	15/23 (65%)	4/8 (50%)
FIRST INCIDENCE	416	416	592	490	633
STATISTICAL TESTS					
LIFE TABLE	P=0.026N*	P=0.239N	P=0.018N*	P=0.008N**	P=0.048N*
POLY 3	P<0.001N**	P=0.401N	P=0.075N	P=0.052N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.500N	P=0.108N	P=0.057N	P<0.001N**
POLY 6	P=0.003N**	P=0.288N	P=0.052N	P=0.056N	P=0.002N**
LOGISTIC REGRESSION	P<0.001N**	P=0.523N	P=0.052N	P=0.029N*	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500	P=0.165N	P=0.086N	P<0.001N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma					
TUMOR RATES					
OVERALL (a)	28/53 (53%)	29/53 (55%)	23/53 (43%)	20/53 (38%)	10/53 (19%)
POLY-3 RATE (b)	28/41.67	29/46.41	23/43.77	20/41.29	10/33.29
POLY-3 PERCENT (g)	67.2%	62.5%	52.5%	48.4%	30.0%
TERMINAL (d)	11/16 (69%)	11/23 (48%)	12/24 (50%)	15/23 (65%)	4/8 (50%)
FIRST INCIDENCE	416	416	592	490	633
STATISTICAL TESTS					
LIFE TABLE	P=0.025N*	P=0.239N	P=0.026N*	P=0.008N**	P=0.048N*
POLY 3	P<0.001N**	P=0.401N	P=0.110N	P=0.052N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.500N	P=0.151N	P=0.057N	P<0.001N**
POLY 6	P=0.003N**	P=0.288N	P=0.078N	P=0.056N	P=0.002N**
LOGISTIC REGRESSION	P<0.001N**	P=0.523N	P=0.075N	P=0.029N*	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500	P=0.218N	P=0.086N	P<0.001N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)	(e)

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Skin Fibroma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	1/53 (2%)	2/53 (4%)	2/53 (4%)	3/53 (6%)	0/53 (0%)
POLY-3 RATE (b)	1/36.39	2/40.22	2/42.04	3/40.39	0/32.33
POLY-3 PERCENT (g)	2.8%	5.0%	4.8%	7.4%	0.0%
TERMINAL (d)	0/16 (0%)	1/23 (4%)	1/24 (4%)	1/23 (4%)	0/8 (0%)
FIRST INCIDENCE	693	668	456	542	---
STATISTICAL TESTS					
LIFE TABLE	P=0.422N	P=0.588	P=0.595	P=0.371	P=0.605N
POLY 3	P=0.363N	P=0.535	P=0.550	P=0.343	P=0.524N
POLY 1.5	P=0.330N	P=0.522	P=0.529	P=0.328	P=0.513N
POLY 6	P=0.412N	P=0.550	P=0.574	P=0.361	P=0.541N
LOGISTIC REGRESSION	P=0.300N	P=0.546	P=0.498	P=0.315	P=0.543N
COCH-ARM / FISHERS	P=0.287N	P=0.500	P=0.500	P=0.309	P=0.500N
ORDER RESTRICTED	P=0.280N	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Skin Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	2/53 (4%)	2/53 (4%)	2/53 (4%)	4/53 (8%)	0/53 (0%)
POLY-3 RATE (b)	2/36.63	2/40.22	2/42.04	4/40.58	0/32.33
POLY-3 PERCENT (g)	5.5%	5.0%	4.8%	9.9%	0.0%
TERMINAL (d)	0/16 (0%)	1/23 (4%)	1/24 (4%)	1/23 (4%)	0/8 (0%)
FIRST INCIDENCE	666	668	456	542	---
STATISTICAL TESTS					
LIFE TABLE	P=0.362N	P=0.607N	P=0.595N	P=0.427	P=0.327N
POLY 3	P=0.320N	P=0.661N	P=0.644N	P=0.384	P=0.265N
POLY 1.5	P=0.281N	P=0.672N	P=0.666N	P=0.366	P=0.252N
POLY 6	P=0.379N	P=0.648N	P=0.621N	P=0.407	P=0.288N
LOGISTIC REGRESSION	P=0.249N	P=0.655N	P=0.693N	P=0.356	P=0.271N
COCH-ARM / FISHERS	P=0.232N	P=0.691N	P=0.691N	P=0.339	P=0.248N
ORDER RESTRICTED	P=0.226N	(e)	(e)	(e)	(e)

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Thyroid Gland: C-Cell Adenoma					
TUMOR RATES					
OVERALL (a)	17/53 (32%)	10/53 (19%)	18/51 (35%)	9/52 (17%)	5/51 (10%)
POLY-3 RATE (b)	17/38.32	10/40.85	18/42.15	9/40.48	5/34.12
POLY-3 PERCENT (g)	44.4%	24.5%	42.7%	22.2%	14.7%
TERMINAL (d)	7/16 (44%)	6/23 (26%)	10/24 (42%)	6/23 (26%)	0/8 (0%)
FIRST INCIDENCE	568	627	617	548	542
STATISTICAL TESTS					
LIFE TABLE	P=0.070N	P=0.020N*	P=0.241N	P=0.012N*	P=0.067N
POLY 3	P=0.005N**	P=0.045N*	P=0.531N	P=0.027N*	P=0.004N**
POLY 1.5	P=0.004N**	P=0.057N	P=0.557	P=0.036N*	P=0.004N**
POLY 6	P=0.009N**	P=0.037N*	P=0.433N	P=0.021N*	P=0.006N**
LOGISTIC REGRESSION	P=0.009N**	P=0.032N*	P=0.443N	P=0.023N*	P=0.009N**
COCH-ARM / FISHERS	P=0.004N**	P=0.090N	P=0.444	P=0.063N	P=0.005N**
ORDER RESTRICTED	P=0.005N**	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

	Females				
Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Thyroid Gland: C-Cell Carcinoma					
TUMOR RATES					
OVERALL (a)	2/53 (4%)	0/53 (0%)	0/51 (0%)	1/52 (2%)	1/51 (2%)
POLY-3 RATE (b)	2/36.76	0/39.99	0/40.30	1/39.36	1/32.48
POLY-3 PERCENT (g)	5.4%	0.0%	0.0%	2.5%	3.1%
TERMINAL (d)	1/16 (6%)	0/23 (0%)	0/24 (0%)	1/23 (4%)	0/8 (0%)
FIRST INCIDENCE	575	---	---	729 (T)	674
STATISTICAL TESTS					
LIFE TABLE	P=0.521	P=0.195N	P=0.181N	P=0.408N	P=0.606N
POLY 3	P=0.563	P=0.218N	P=0.217N	P=0.476N	P=0.543N
POLY 1.5	P=0.589	P=0.225N	P=0.229N	P=0.486N	P=0.526N
POLY 6	P=0.528	P=0.211N	P=0.203N	P=0.466N	P=0.572N
LOGISTIC REGRESSION	P=0.596	P=0.228N	P=0.235N	P=0.475N	P=0.537N
COCH-ARM / FISHERS	P=0.621	P=0.248N	P=0.257N	P=0.507N	P=0.515N
ORDER RESTRICTED	P=0.216N	(e)	(e)	(e)	(e)

	Females				
Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Thyroid Gland: C-Cell Carcinoma or Adenoma					
TUMOR RATES					
OVERALL (a)	18/53 (34%)	10/53 (19%)	18/51 (35%)	10/52 (19%)	6/51 (12%)
POLY-3 RATE (b)	18/38.83	10/40.85	18/42.15	10/40.48	6/34.33
POLY-3 PERCENT (g)	46.4%	24.5%	42.7%	24.7%	17.5%
TERMINAL (d)	7/16 (44%)	6/23 (26%)	10/24 (42%)	7/23 (30%)	0/8 (0%)
FIRST INCIDENCE	568	627	617	548	542
STATISTICAL TESTS					
LIFE TABLE	P=0.115N	P=0.013N*	P=0.186N	P=0.012N*	P=0.081N
POLY 3	P=0.011N*	P=0.029N*	P=0.457N	P=0.031N*	P=0.006N**
POLY 1.5	P=0.008N**	P=0.037N*	P=0.540N	P=0.040N*	P=0.005N**
POLY 6	P=0.018N*	P=0.025N*	P=0.370N	P=0.026N*	P=0.009N**
LOGISTIC REGRESSION	P=0.017N*	P=0.021N*	P=0.377N	P=0.026N*	P=0.011N*
COCH-ARM / FISHERS	P=0.007N**	P=0.061N	P=0.525	P=0.068N	P=0.006N**
ORDER RESTRICTED	P=0.006N**	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	Females TERT.MIX CONTROL	 TERT.MIX TEQ=10	 TERT.MIX TEQ=22	 TERT.MIX TEQ=46	 TERT.MIX TEQ=100
Thyroid Gland: Follicular Cell Carcinoma or Adenoma					
TUMOR RATES					
OVERALL (a)	0/53 (0%)	0/53 (0%)	2/51 (4%)	0/52 (0%)	1/51 (2%)
POLY-3 RATE (b)	0/36.25	0/39.99	2/40.56	0/39.36	1/32.43
POLY-3 PERCENT (g)	0.0%	0.0%	4.9%	0.0%	3.1%
TERMINAL (d)	0/16 (0%)	0/23 (0%)	1/24 (4%)	0/23 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	659	---	689
STATISTICAL TESTS					
LIFE TABLE	P=0.298	(e)	P=0.317	(e)	P=0.424
POLY 3	P=0.399	(e)	P=0.263	(e)	P=0.478
POLY 1.5	P=0.413	(e)	P=0.247	(e)	P=0.487
POLY 6	P=0.376	(e)	P=0.283	(e)	P=0.463
LOGISTIC REGRESSION	P=0.375	(e)	P=0.265	(e)	P=0.460
COCH-ARM / FISHERS	P=0.425	(e)	P=0.238	(e)	P=0.490
ORDER RESTRICTED	P=0.284	(e)	(e)	(e)	(e)

Dose	Females TERT.MIX CONTROL	 TERT.MIX TEQ=10	 TERT.MIX TEQ=22	 TERT.MIX TEQ=46	 TERT.MIX TEQ=100
Uterus Carcinoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	1/53 (2%)	1/53 (2%)	2/53 (4%)	2/53 (4%)	1/53 (2%)
POLY-3 RATE (b)	1/36.52	1/39.99	2/41.29	2/40.11	1/32.88
POLY-3 PERCENT (g)	2.7%	2.5%	4.8%	5.0%	3.0%
TERMINAL (d)	0/16 (0%)	1/23 (4%)	2/24 (8%)	1/23 (4%)	0/8 (0%)
FIRST INCIDENCE	658	729 (T)	729 (T)	505	562
STATISTICAL TESTS					
LIFE TABLE	P=0.465	P=0.702N	P=0.621	P=0.577	P=0.726
POLY 3	P=0.549	P=0.741N	P=0.543	P=0.533	P=0.738
POLY 1.5	P=0.582	P=0.748N	P=0.524	P=0.521	P=0.748
POLY 6	P=0.501	P=0.733N	P=0.563	P=0.547	P=0.720
LOGISTIC REGRESSION	P=0.596	P=0.736N	P=0.572	P=0.501	P=0.761
COCH-ARM / FISHERS	P=0.601N	P=0.752N	P=0.500	P=0.500	P=0.752N
ORDER RESTRICTED	P=0.608	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Uterus Leiomyoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	0/53 (0%)	0/53 (0%)	2/53 (4%)	0/53 (0%)	0/53 (0%)
POLY-3 RATE (b)	0/36.25	0/39.99	2/41.55	0/39.44	0/32.33
POLY-3 PERCENT (g)	0.0%	0.0%	4.8%	0.0%	0.0%
TERMINAL (d)	0/16 (0%)	0/23 (0%)	1/24 (4%)	0/23 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	659	---	---
STATISTICAL TESTS					
LIFE TABLE	P=0.607N	(e)	P=0.317	(e)	(e)
POLY 3	P=0.503N	(e)	P=0.268	(e)	(e)
POLY 1.5	P=0.502N	(e)	P=0.254	(e)	(e)
POLY 6	P=0.504N	(e)	P=0.286	(e)	(e)
LOGISTIC REGRESSION	P=0.547N	(e)	P=0.271	(e)	(e)
COCH-ARM / FISHERS	P=0.499N	(e)	P=0.248	(e)	(e)
ORDER RESTRICTED	P=0.431	(e)	(e)	(e)	(e)

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
Uterus Polyp Stromal					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	4/53 (8%)	1/53 (2%)	3/53 (6%)	3/53 (6%)	2/53 (4%)
POLY-3 RATE (b)	4/36.88	1/39.99	3/41.39	3/39.57	2/33.09
POLY-3 PERCENT (g)	10.9%	2.5%	7.3%	7.6%	6.0%
TERMINAL (d)	1/16 (6%)	1/23 (4%)	2/24 (8%)	2/23 (9%)	0/8 (0%)
FIRST INCIDENCE	627	729 (T)	702	697	562
STATISTICAL TESTS					
LIFE TABLE	P=0.492	P=0.114N	P=0.333N	P=0.363N	P=0.489N
POLY 3	P=0.512N	P=0.153N	P=0.437N	P=0.461N	P=0.387N
POLY 1.5	P=0.480N	P=0.161N	P=0.464N	P=0.474N	P=0.364N
POLY 6	P=0.552N	P=0.145N	P=0.408N	P=0.447N	P=0.424N
LOGISTIC REGRESSION	P=0.551N	P=0.142N	P=0.398N	P=0.433N	P=0.388N
COCH-ARM / FISHERS	P=0.431N	P=0.181N	P=0.500N	P=0.500N	P=0.339N
ORDER RESTRICTED	P=0.373N	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

	Females				
Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
Uterus					
Schwannoma Malignant					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	1/53 (2%)	0/53 (0%)	1/53 (2%)	2/53 (4%)	1/53 (2%)
POLY-3 RATE (b)	1/36.84	0/39.99	1/41.70	2/40.01	1/33.16
POLY-3 PERCENT (g)	2.7%	0.0%	2.4%	5.0%	3.0%
TERMINAL (d)	0/16 (0%)	0/23 (0%)	0/24 (0%)	0/23 (0%)	0/8 (0%)
FIRST INCIDENCE	540	---	609	619	409
STATISTICAL TESTS					
LIFE TABLE	P=0.385	P=0.472N	P=0.725N	P=0.535	P=0.753
POLY 3	P=0.372	P=0.484N	P=0.733N	P=0.529	P=0.738
POLY 1.5	P=0.407	P=0.489N	P=0.745N	P=0.518	P=0.749
POLY 6	P=0.323	P=0.477N	P=0.718N	P=0.543	P=0.719
LOGISTIC REGRESSION	P=0.490	P=0.533N	P=0.751	P=0.493	P=0.733N
COCH-ARM / FISHERS	P=0.455	P=0.500N	P=0.752N	P=0.500	P=0.752N
ORDER RESTRICTED	P=0.423	(e)	(e)	(e)	(e)

	Females				
Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
All Organs					
Histiocytic Sarcoma					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	0/53 (0%)	0/53 (0%)	0/53 (0%)	0/53 (0%)	4/53 (8%)
POLY-3 RATE (b)	0/36.25	0/39.99	0/41.29	0/39.44	4/34.26
POLY-3 PERCENT (g)	0.0%	0.0%	0.0%	0.0%	11.7%
TERMINAL (d)	0/16 (0%)	0/23 (0%)	0/24 (0%)	0/23 (0%)	1/8 (13%)
FIRST INCIDENCE	---	---	---	---	312
STATISTICAL TESTS					
LIFE TABLE	P<0.001 **	(e)	(e)	(e)	P=0.036 *
POLY 3	P<0.001 **	(e)	(e)	(e)	P=0.051
POLY 1.5	P<0.001 **	(e)	(e)	(e)	P=0.056
POLY 6	P<0.001 **	(e)	(e)	(e)	P=0.044 *
LOGISTIC REGRESSION	P<0.001 **	(e)	(e)	(e)	P=0.072
COCH-ARM / FISHERS	P<0.001 **	(e)	(e)	(e)	P=0.059
ORDER RESTRICTED	P<0.001 **	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
All Organs Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	2/53 (4%)	1/53 (2%)	0/53 (0%)	1/53 (2%)	1/53 (2%)
POLY-3 RATE (b)	2/36.91	1/39.99	0/41.29	1/39.84	1/32.54
POLY-3 PERCENT (g)	5.4%	2.5%	0.0%	2.5%	3.1%
TERMINAL (d)	1/16 (6%)	1/23 (4%)	0/24 (0%)	0/23 (0%)	0/8 (0%)
FIRST INCIDENCE	508	729 (T)	---	616	674
STATISTICAL TESTS					
LIFE TABLE	P=0.648	P=0.406N	P=0.183N	P=0.438N	P=0.596N
POLY 3	P=0.558N	P=0.472N	P=0.213N	P=0.473N	P=0.544N
POLY 1.5	P=0.546N	P=0.481N	P=0.223N	P=0.483N	P=0.524N
POLY 6	P=0.567N	P=0.461N	P=0.201N	P=0.461N	P=0.574N
LOGISTIC REGRESSION	P=0.546N	P=0.484N	P=0.240N	P=0.505N	P=0.519N
COCH-ARM / FISHERS	P=0.525N	P=0.500N	P=0.248N	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.316N	(e)	(e)	(e)	(e)

Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
			Females		
All Organs Benign Tumors					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	45/53 (85%)	43/53 (81%)	46/53 (87%)	43/53 (81%)	36/53 (68%)
POLY-3 RATE (b)	45/48.33	43/49.69	46/50.24	43/47.21	36/42.01
POLY-3 PERCENT (g)	93.1%	86.5%	91.6%	91.1%	85.7%
TERMINAL (d)	14/16 (88%)	18/23 (78%)	22/24 (92%)	21/23 (91%)	7/8 (88%)
FIRST INCIDENCE	176	362	263	333	409
STATISTICAL TESTS					
LIFE TABLE	P=0.104	P=0.082N	P=0.080N	P=0.066N	P=0.320
POLY 3	P=0.242N	P=0.211N	P=0.539N	P=0.506N	P=0.162N
POLY 1.5	P=0.077N	P=0.267N	P=0.645N	P=0.445N	P=0.077N
POLY 6	P=0.546N	P=0.182N	P=0.473N	P=0.580N	P=0.384N
LOGISTIC REGRESSION	P=0.037N*	P=0.268N	P=0.610	P=0.230N	P=0.046N*
COCH-ARM / FISHERS	P=0.010N*	P=0.398N	P=0.500	P=0.398N	P=0.033N*
ORDER RESTRICTED	P=0.167N	(e)	(e)	(e)	(e)

Statistical Analysis of Primary Tumors in Rats(SPRAGUE-DAWLEY) - TOXIC EQUIVALENCY FACTOR EVALUATION (DIOX
Terminal Sacrifice at 105 weeks

	Females				
Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
All Organs Malignant Tumors					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	18/53 (34%)	14/53 (26%)	19/53 (36%)	21/53 (40%)	23/53 (43%)
POLY-3 RATE (b)	18/43.25	14/45.06	19/44.70	21/45.77	23/41.67
POLY-3 PERCENT (g)	41.6%	31.1%	42.5%	45.9%	55.2%
TERMINAL (d)	5/16 (31%)	7/23 (30%)	8/24 (33%)	9/23 (39%)	2/8 (25%)
FIRST INCIDENCE	218	227	203	276	312
STATISTICAL TESTS					
LIFE TABLE	P=0.003 **	P=0.126N	P=0.307N	P=0.508N	P=0.078
POLY 3	P=0.029 *	P=0.204N	P=0.553	P=0.423	P=0.140
POLY 1.5	P=0.038 *	P=0.216N	P=0.524	P=0.394	P=0.162
POLY 6	P=0.023 *	P=0.205N	P=0.585	P=0.455	P=0.117
LOGISTIC REGRESSION	P=0.092	P=0.354N	P=0.489	P=0.295	P=0.233
COCH-ARM / FISHERS	P=0.068	P=0.263N	P=0.500	P=0.344	P=0.213
ORDER RESTRICTED	P=0.053	(e)	(e)	(e)	(e)

	Females				
Dose	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
All Organs Malignant and Benign Tumors					
TUMOR RATES	#	#	#	#	#
OVERALL (a)	51/53 (96%)	46/53 (87%)	50/53 (94%)	50/53 (94%)	45/53 (85%)
POLY-3 RATE (b)	51/53.00	46/51.78	50/52.00	50/51.35	45/47.10
POLY-3 PERCENT (g)	96.2%	88.8%	96.2%	97.4%	95.6%
TERMINAL (d)	14/16 (88%)	18/23 (78%)	22/24 (92%)	22/23 (96%)	8/8 (100%)
FIRST INCIDENCE	176	227	203	276	312
STATISTICAL TESTS					
LIFE TABLE	P=0.022 *	P=0.045N*	P=0.054N	P=0.094N	P=0.196
POLY 3	P=0.319	P=0.136N	P=0.686N	P=0.591	P=0.649N
POLY 1.5	P=0.574N	P=0.109N	P=0.684N	P=0.679	P=0.348N
POLY 6	P=0.153	P=0.172N	P=0.686N	P=0.531	P=0.557
LOGISTIC REGRESSION	P=0.139N	P=0.105N	P=0.480N	P=0.478N	P=0.064N
COCH-ARM / FISHERS	P=0.081N	P=0.080N	P=0.500N	P=0.500N	P=0.046N*
ORDER RESTRICTED	P=0.299	(e)	(e)	(e)	(e)

(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]
TOXIC EQUIVALENCY FACTOR EVALUATION (DIOXIN MIXTURE)

FINAL #2

Facility: Battelle Columbus Laboratory

Chemical CAS #: TEFDIOXINMIX

Lock Date: 09/12/01

Cage Range: All

Reasons For Removal: 25018 Dosing Accident
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

Removal Date Range: All

Treatment Groups:

Include 001	TERT.MIXCONTROL
Include 002	TERT.MIXTEQ=10
Include 003	TERT.MIXTEQ=22
Include 004	TERT.MIXTEQ=46
Include 005	TERT.MIXTEQ=100

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)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
DISPOSITION SUMMARY					
Animals Initially In Study	98	98	98	98	98
Early Deaths					
Moribund Sacrifice	26	25	22	25	33
Natural Death	11	5	6	4	10
Dosing Accident			1	1	2
Survivors					
Terminal Sacrifice	16	23	24	23	8
Animals Examined Microscopically	53	53	53	53	53
ALIMENTARY SYSTEM					
Esophagus	(53)	(53)	(53)	(53)	(53)
Muscularis, Inflammation		2 [1.0]	1 [2.0]	1 [1.0]	
Intestine Large, Colon	(53)	(52)	(53)	(53)	(51)
Parasite Metazoan			1		
Intestine Large, Rectum	(52)	(53)	(53)	(53)	(52)
Parasite Metazoan	2	4	5	1	
Artery, Inflammation, Chronic Active				2 [2.5]	3 [3.0]
Serosa, Inflammation					1 [3.0]
Intestine Large, Cecum	(51)	(53)	(53)	(53)	(51)
Artery, Inflammation, Chronic Active					1 [2.0]
Intestine Small, Duodenum	(52)	(53)	(53)	(53)	(52)
Serosa, Inflammation, Chronic Active					1 [3.0]
Liver	(53)	(53)	(53)	(53)	(51)
Angiectasis	3 [1.7]	2 [1.5]			3 [1.0]
Basophilic Focus	9	14	10	5	8
Basophilic Focus, Multiple	15	12	3	7	8
Cholangiofibrosis		2 [1.0]	3 [2.0]	4 [2.5]	17 [2.3]
Clear Cell Focus		1	1		
Clear Cell Focus, Multiple	1			1	
Degeneration, Cystic	1 [1.0]			1 [1.0]	2 [1.0]
Eosinophilic Focus	4	2	5	5	
Eosinophilic Focus, Multiple	1	7	6	15	19
Fatty Change, Diffuse	3 [2.3]	5 [1.0]	14 [1.0]	34 [1.1]	36 [1.3]
Fatty Change, Focal	3 [1.3]	4 [1.5]	7 [1.6]	2 [1.5]	1 [1.0]
Hematopoietic Cell Proliferation	16 [1.1]	18 [1.1]	19 [1.1]	8 [1.0]	9 [1.1]
Hepatodiaphragmatic Nodule			1		
Hyperplasia, Nodular		1	3	11	38
Inflammation	36 [1.1]	50 [1.1]	45 [1.2]	50 [1.3]	50 [1.3]
Karyomegaly				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]
TOXIC EQUIVALENCY FACTOR EVALUATION (DIOXIN MIXTURE)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
ALIMENTARY SYSTEM - CONT					
Mixed Cell Focus	4	5	5	1	
Mixed Cell Focus, Multiple	17	27	30	35	17
Necrosis	3 [1.7]	1 [2.0]	9 [2.2]	3 [1.7]	15 [2.2]
Pigmentation	4 [1.5]	35 [1.3]	41 [1.2]	48 [1.9]	51 [2.2]
Toxic Hepatopathy		5 [1.0]	14 [1.0]	38 [1.6]	47 [3.1]
Bile Duct, Cyst	1 [3.0]	3 [2.7]	3 [2.3]	4 [2.3]	9 [2.0]
Bile Duct, Dilatation	1 [1.0]				1 [3.0]
Bile Duct, Fibrosis	3 [1.7]	2 [1.0]	1 [1.0]	5 [1.4]	1 [2.0]
Bile Duct, Hyperplasia	2 [1.5]	3 [1.3]	5 [1.4]	25 [1.4]	42 [1.9]
Centrilobular, Degeneration	3 [1.7]	2 [2.0]	1 [3.0]	1 [2.0]	6 [2.2]
Centrilobular, Fibrosis					1 [1.0]
Hepatocyte, Hypertrophy	1 [1.0]	27 [1.1]	34 [1.2]	46 [1.5]	50 [3.0]
Hepatocyte, Multinucleated		12 [1.0]	10 [1.2]	39 [1.5]	51 [2.1]
Oval Cell, Hyperplasia		1 [1.0]	1 [1.0]	26 [1.4]	42 [2.2]
Portal, Fibrosis					11 [1.9]
Serosa, Fibrosis					1 [2.0]
Serosa, Inflammation, Chronic	1 [2.0]				
Mesentery		(1)	(2)	(6)	(8)
Inflammation, Chronic Active					2 [3.0]
Necrosis			1 [3.0]		
Artery, Inflammation, Chronic Active		1 [4.0]		3 [3.7]	6 [3.7]
Fat, Necrosis			1 [3.0]	2 [3.0]	
Oral Mucosa	(10)	(18)	(19)	(29)	(31)
Gingival, Hyperplasia, Squamous	8 [1.5]	17 [1.5]	18 [1.4]	26 [1.6]	30 [1.6]
Pancreas	(52)	(53)	(53)	(53)	(51)
Degeneration	1 [2.0]				
Inflammation, Chronic Active	3 [1.7]	1 [3.0]	6 [1.3]	7 [1.7]	16 [1.8]
Inflammation, Granulomatous				1 [2.0]	
Acinus, Atrophy	3 [1.3]	2 [1.0]	7 [1.7]	7 [1.7]	20 [2.0]
Acinus, Hyperplasia	2 [1.5]		1 [2.0]		
Acinus, Vacuolization Cytoplasmic	1 [1.0]		3 [1.3]	15 [1.0]	30 [1.1]
Artery, Inflammation, Chronic Active		6 [2.2]	3 [1.7]	8 [2.6]	14 [2.9]
Duct, Cyst			1 [2.0]		
Duct, Dilatation					5 [3.0]
Duct, Inflammation, Chronic Active					2 [3.5]
Salivary Glands	(53)	(53)	(53)	(53)	(53)
Atrophy	1 [3.0]				
Inflammation	2 [2.0]			1 [3.0]	
Mineralization				1 [2.0]	
Stomach, Forestomach	(53)	(53)	(53)	(53)	(52)
Cyst				1 [3.0]	1 [3.0]
Diverticulum				1	
Edema	1 [3.0]		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)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
ALIMENTARY SYSTEM - CONT					
Erosion			1 [1.0]		
Hyperkeratosis			2 [2.5]	2 [2.0]	
Hyperplasia, Squamous	5 [2.4]	1 [2.0]	4 [2.3]	9 [1.7]	6 [2.5]
Inflammation	2 [2.5]		2 [2.5]	1 [3.0]	3 [1.7]
Mineralization	1 [2.0]		4 [1.5]	2 [1.0]	
Ulcer	3 [3.0]		2 [2.5]	1 [2.0]	2 [2.0]
Artery, Inflammation, Chronic Active				2 [2.5]	1 [3.0]
Stomach, Glandular	(53)	(53)	(53)	(53)	(52)
Erosion	1 [2.0]				
Mineralization	2 [2.0]	4 [1.5]	3 [1.3]	3 [1.7]	1 [2.0]
Artery, Inflammation, Chronic Active					2 [3.0]
Tongue	(1)				(1)
Infiltration Cellular					1 [3.0]
Tooth	(24)	(23)	(27)	(37)	(30)
Peridontal Tissue, Inflammation	23 [1.1]	21 [1.3]	22 [1.2]	34 [1.3]	30 [1.7]
CARDIOVASCULAR SYSTEM					
Blood Vessel	(53)	(53)	(53)	(52)	(53)
Aorta, Mineralization				1 [2.0]	3 [2.3]
Heart	(53)	(53)	(53)	(52)	(53)
Cardiomyopathy	11 [1.0]	26 [1.0]	31 [1.1]	30 [1.1]	32 [1.1]
Inflammation, Suppurative	1 [3.0]				1 [4.0]
Mineralization				1 [2.0]	
Necrosis					1 [3.0]
Thrombosis	1 [3.0]				1 [3.0]
Artery, Degeneration				1 [2.0]	1 [2.0]
Artery, Inflammation, Chronic Active				1 [2.0]	1 [2.0]
ENDOCRINE SYSTEM					
Adrenal Cortex	(52)	(53)	(53)	(53)	(51)
Angiectasis	15 [1.7]	20 [1.6]	18 [1.5]	17 [1.6]	8 [1.6]
Atrophy		3 [2.3]			18 [2.7]
Degeneration, Cystic	9 [2.4]	15 [2.3]	19 [2.3]	25 [2.3]	16 [2.1]
Hematopoietic Cell Proliferation			1 [1.0]		1 [1.0]
Hyperplasia	12 [2.5]	26 [2.4]	23 [2.8]	25 [2.6]	21 [2.5]
Hypertrophy	44 [2.1]	45 [2.2]	47 [2.4]	46 [2.5]	45 [2.3]
Inflammation				1 [2.0]	
Mineralization		1 [3.0]			1 [3.0]
Necrosis	2 [3.0]		2 [2.5]		2 [2.5]

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)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
ENDOCRINE SYSTEM - CONT					
Thrombosis		1 [3.0]			
Vacuolization Cytoplasmic	6 [1.2]	13 [1.5]	11 [1.5]	7 [1.7]	15 [1.5]
Capsule, Inflammation				1 [2.0]	1 [3.0]
Adrenal Medulla	(52)	(53)	(53)	(53)	(51)
Hyperplasia	10 [2.2]	21 [2.0]	12 [1.8]	15 [1.7]	9 [1.6]
Islets, Pancreatic	(52)	(53)	(53)	(53)	(51)
Hyperplasia			1 [2.0]	2 [2.0]	
Pituitary Gland	(53)	(53)	(53)	(53)	(53)
Angiectasis	6 [1.7]		1 [1.0]	2 [2.5]	3 [2.3]
Cyst	1 [2.0]		1 [2.0]	2 [1.5]	
Cytoplasmic Alteration		3 [1.3]			
Hemorrhage	1 [2.0]				
Vacuolization Cytoplasmic		1 [1.0]	2 [1.0]	3 [1.3]	1 [1.0]
Pars Distalis, Hyperplasia	18 [2.5]	19 [2.3]	24 [2.5]	20 [2.5]	19 [2.1]
Pars Intermedia, Cyst			1 [3.0]		
Thyroid Gland	(53)	(53)	(51)	(52)	(51)
C-Cell, Hyperplasia	24 [2.3]	24 [2.3]	20 [2.1]	18 [2.3]	14 [2.0]
Follicular Cell, Hyperplasia	1 [1.0]				
Follicular Cell, Hypertrophy	4 [1.5]	13 [1.1]	12 [1.5]	18 [1.7]	23 [1.9]
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Clitoral Gland	(51)	(53)	(53)	(51)	(50)
Hyperplasia, Squamous				1 [2.0]	
Inflammation	42 [1.7]	40 [1.7]	37 [1.3]	33 [1.3]	29 [1.1]
Duct, Cyst	39 [2.3]	41 [2.5]	44 [2.1]	39 [2.3]	44 [2.3]
Ovary	(52)	(52)	(53)	(53)	(51)
Atrophy	44 [4.0]	44 [4.0]	43 [4.0]	49 [3.9]	40 [4.0]
Cyst	8 [2.6]	16 [2.4]	20 [2.3]	14 [2.3]	7 [2.3]
Fibrosis		1 [3.0]			
Hemorrhage					1 [2.0]
Inflammation, Chronic Active		2 [3.0]	1 [4.0]	2 [3.5]	5 [3.6]
Artery, Inflammation, Chronic Active					1 [4.0]
Oviduct		(2)		(2)	(5)
Cyst		2 [2.0]			1 [2.0]
Inflammation, Chronic Active				2 [4.0]	4 [4.0]
Uterus	(52)	(53)	(53)	(53)	(51)

a Number of animals examined microscopically at site and number of animals with lesion
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INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
TOXIC EQUIVALENCY FACTOR EVALUATION (DIOXIN MIXTURE)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
GENITAL SYSTEM - CONT					
Adenomyosis		1 [2.0]	1 [2.0]	2 [2.0]	1 [2.0]
Hemorrhage	1 [3.0]				1 [2.0]
Inflammation, Chronic Active	1 [2.0]	1 [3.0]	1 [3.0]	1 [4.0]	3 [3.0]
Inflammation, Suppurative	6 [1.8]	5 [2.2]	9 [1.8]	13 [1.8]	6 [3.2]
Metaplasia, Squamous	21 [2.0]	32 [2.2]	32 [2.3]	35 [2.4]	30 [2.4]
Thrombosis				1 [3.0]	
Ulcer		1 [2.0]		1 [3.0]	
Cervix, Hyperplasia, Stromal	1 [4.0]				
Endometrium, Fibrosis					1 [2.0]
Endometrium, Hyperplasia, Cystic	37 [1.9]	35 [2.2]	34 [2.1]	33 [2.2]	23 [2.1]
Epithelium, Necrosis	1 [4.0]				
HEMATOPOIETIC SYSTEM					
Bone Marrow	(53)	(53)	(53)	(53)	(53)
Hyperplasia	36 [3.1]	36 [2.8]	34 [2.7]	41 [3.0]	48 [3.0]
Lymph Node	(4)	(1)	(2)	(9)	(11)
Lumbar, Ectasia			1 [2.0]		
Lumbar, Hemorrhage			1 [2.0]		
Lumbar, Hyperplasia, Lymphoid			1 [2.0]		1 [2.0]
Lumbar, Hyperplasia, Plasma Cell	1 [2.0]			3 [2.3]	
Mediastinal, Ectasia		1 [2.0]		4 [2.0]	2 [2.0]
Mediastinal, Fibrosis				1 [2.0]	
Mediastinal, Hemorrhage				1 [2.0]	2 [2.0]
Mediastinal, Hyperplasia, Histiocytic				1 [2.0]	1 [2.0]
Mediastinal, Hyperplasia, Lymphoid					2 [2.5]
Mediastinal, Hyperplasia, Plasma Cell					3 [2.3]
Pancreatic, Ectasia	1 [3.0]				
Pancreatic, Hyperplasia, Histiocytic					1 [2.0]
Popliteal, Hyperplasia, Plasma Cell				1 [3.0]	
Renal, Hyperplasia, Histiocytic	1 [3.0]				
Lymph Node, Mandibular	(53)	(53)	(53)	(53)	(53)
Ectasia		1 [2.0]	1 [2.0]	2 [3.0]	
Hemorrhage				1 [1.0]	
Hyperplasia, Plasma Cell	31 [2.1]	42 [2.1]	30 [2.1]	22 [2.3]	27 [2.3]
Necrosis, Focal				1 [3.0]	
Lymph Node, Mesenteric	(52)	(53)	(53)	(53)	(50)
Ectasia	1 [2.0]				
Hemorrhage	1 [3.0]				1 [2.0]
Hyperplasia, Histiocytic				1 [2.0]	1 [2.0]
Hyperplasia, Lymphoid			1 [4.0]		
Pigmentation				1 [3.0]	

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INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
TOXIC EQUIVALENCY FACTOR EVALUATION (DIOXIN MIXTURE)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
HEMATOPOIETIC SYSTEM - CONT					
Spleen	(52)	(53)	(53)	(53)	(51)
Hematopoietic Cell Proliferation	43 [1.8]	48 [1.5]	42 [1.5]	44 [1.6]	42 [1.6]
Hemorrhage					1 [2.0]
Inflammation, Suppurative					1 [2.0]
Necrosis	1 [3.0]				1 [3.0]
Pigmentation	45 [1.4]	50 [1.3]	52 [1.4]	47 [1.4]	46 [1.1]
Lymphoid Follicle, Atrophy	1 [2.0]	2 [3.0]	3 [2.0]	2 [2.5]	3 [2.3]
Red Pulp, Atrophy		1 [2.0]	3 [2.0]		
Thymus	(52)	(48)	(50)	(53)	(50)
Atrophy	32 [2.3]	43 [2.9]	45 [3.3]	50 [3.7]	48 [3.9]
Cyst	2 [2.5]				
Ectopic Thyroid				1 [4.0]	
Hemorrhage				1 [3.0]	
INTEGUMENTARY SYSTEM					
Mammary Gland	(53)	(53)	(53)	(53)	(52)
Cyst		3 [2.7]	1 [2.0]	1 [3.0]	
Hyperplasia	22 [1.2]	7 [1.6]	14 [1.1]	12 [1.0]	9 [1.0]
Inflammation, Granulomatous	3 [1.3]	4 [1.8]	1 [3.0]	3 [3.0]	1 [2.0]
Inflammation, Suppurative				1 [2.0]	
Skin	(53)	(53)	(53)	(53)	(53)
Cyst Epithelial Inclusion		2	1	3	3
Hyperkeratosis			1 [2.0]		
Inflammation, Suppurative				1 [2.0]	
Ulcer				1 [3.0]	1 [2.0]
Hair Follicle, Atrophy		1 [4.0]			
MUSCULOSKELETAL SYSTEM					
Bone	(53)	(53)	(53)	(53)	(53)
Mineralization			1 [1.0]		
NERVOUS SYSTEM					
Brain	(53)	(53)	(53)	(53)	(53)
Edema				1 [1.0]	3 [2.0]
Gliosis	1 [3.0]				1 [3.0]
Hemorrhage		1 [2.0]			
Hydrocephalus	1 [1.0]	4 [1.3]	2 [2.0]	2 [2.0]	

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INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
TOXIC EQUIVALENCY FACTOR EVALUATION (DIOXIN MIXTURE)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
NERVOUS SYSTEM - CONT					
Inflammation, Granulomatous			1 [2.0]		
Mineralization	1 [2.0]		1 [1.0]	1 [1.0]	
Necrosis					3 [1.7]
Artery, Degeneration					1 [3.0]
RESPIRATORY SYSTEM					
Lung	(53)	(53)	(53)	(53)	(53)
Congestion			1 [3.0]	1 [3.0]	
Cyst					1 [3.0]
Edema			2 [2.0]	2 [2.5]	1 [2.0]
Hemorrhage			1 [2.0]		1 [1.0]
Infiltration Cellular, Histiocyte	43 [1.9]	50 [1.9]	48 [1.6]	48 [1.6]	50 [1.4]
Inflammation	4 [1.5]	2 [2.0]	3 [2.0]	1 [3.0]	2 [3.0]
Metaplasia, Squamous	2 [2.0]		2 [2.0]	8 [2.0]	11 [1.9]
Mineralization				1 [1.0]	
Alveolar Epithelium, Hyperplasia	21 [1.3]	25 [1.0]	10 [1.3]	2 [1.0]	2 [1.5]
Alveolar Epithelium, Metaplasia, Bronchiolar		20 [1.8]	33 [1.6]	41 [1.8]	40 [1.9]
Perivascular, Inflammation, Chronic Active					1 [3.0]
Nose	(53)	(53)	(53)	(53)	(53)
Inflammation	1 [1.0]	2 [1.0]	2 [2.0]	1 [1.0]	1 [2.0]
Goblet Cell, Hyperplasia			2 [2.0]	1 [2.0]	
Goblet Cell, Septum, Hyperplasia				1 [2.0]	
Nasolacrimal Duct, Inflammation				1 [3.0]	
Respiratory Epithelium, Hyperplasia		1 [1.0]		4 [1.8]	
Turbinate, Cyst				1 [2.0]	
Turbinate, Respiratory Epithelium, Hyperplasia					1 [2.0]
SPECIAL SENSES SYSTEM					
Eye	(53)	(53)	(53)	(53)	(53)
Anterior Chamber, Ciliary Body, Iris, Inflammation, Suppurative					1 [2.0]
Cornea, Inflammation, Suppurative					1 [3.0]
Lens, Degeneration		1 [4.0]			
Retina, Atrophy	1 [3.0]	1 [4.0]	2 [2.0]	1 [2.0]	3 [2.0]
Harderian Gland	(53)	(53)	(52)	(53)	(53)
Inflammation	8 [1.1]	11 [1.0]	4 [1.3]	5 [1.0]	8 [1.4]

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INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]
TOXIC EQUIVALENCY FACTOR EVALUATION (DIOXIN MIXTURE)

SPRAGUE-DAWLEY RATS FEMALE	TERT.MIX CONTROL	TERT.MIX TEQ=10	TERT.MIX TEQ=22	TERT.MIX TEQ=46	TERT.MIX TEQ=100
URINARY SYSTEM					
Kidney	(52)	(53)	(53)	(53)	(51)
Calculus Micro Observation Only	9 [1.6]	5 [1.8]	8 [1.6]	4 [2.0]	1 [2.0]
Casts Protein			1 [1.0]	1 [1.0]	
Cyst		1 [2.0]		1 [3.0]	
Developmental Malformation					1
Fibrosis					1 [2.0]
Inflammation, Chronic				1 [4.0]	
Inflammation, Chronic Active	1 [2.0]	1 [4.0]	1 [3.0]		
Inflammation, Suppurative	3 [1.3]	2 [1.0]	3 [1.0]	3 [1.7]	6 [2.8]
Mineralization	41 [1.0]	48 [1.0]	47 [1.1]	42 [1.1]	35 [1.2]
Nephropathy	26 [1.1]	41 [1.2]	40 [1.3]	47 [1.3]	49 [2.1]
Pelvis, Dilatation	2 [2.0]		1 [3.0]	1 [3.0]	1 [2.0]
Pelvis, Inflammation	2 [2.0]	1 [1.0]	1 [3.0]	2 [2.5]	1 [2.0]
Renal Tubule, Hyperplasia				2 [1.5]	
Renal Tubule, Necrosis	1 [2.0]		1 [2.0]		
Transitional Epithelium, Hyperplasia	5 [2.0]	5 [1.8]	8 [1.9]	10 [2.0]	8 [2.5]
Ureter	(1)		(1)	(1)	(1)
Cyst	1 [3.0]				
Inflammation			1 [2.0]		
Metaplasia, Squamous				1 [2.0]	
Transitional Epithelium, Hyperplasia			1 [3.0]	1 [3.0]	
Urinary Bladder	(52)	(52)	(53)	(53)	(50)
Edema				1 [2.0]	
Hemorrhage					1 [2.0]
Inflammation	12 [1.0]	3 [1.0]	4 [1.5]	8 [1.4]	5 [2.0]
Metaplasia, Squamous				1 [3.0]	
Transitional Epithelium, Hyperplasia			1 [2.0]	3 [2.7]	4 [1.8]

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END OF REPORT