Experiment Number: 97011-20 Test Type: 26-WEEK Route: GAVAGE Species/Strain: Mouse/FVB/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Transgenic model evaluation (DES)

CAS Number: 56-53-1

Date Report Requested: 10/21/2014 Time Report Requested: 17:34:07 First Dose M/F: NA / NA Lab: BAT

C Number:	C97011H
Lock Date:	01/05/2001
Cage Range:	All
Date Range:	All
Reasons For Removal:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Both
PWG Approval Date	NONE

Test Type: 26-WEEK

Route: GAVAGE

Species/Strain: Mouse/FVB/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

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CAS Number: 56-53-1

Date Report Requested: 10/21/2014 Time Report Requested: 17:34:07 First Dose M/F: NA / NA Lab: BAT

FVB/N Mouse MALE	0 UG/KG	480 UG/KG
Disposition Summary		
Animals Initially In Study	15	15
Early Deaths		
Survivors		
Terminal Sacrifice	15	15
Animals Examined Microscopically	15	15
ALIMENTARY SYSTEM		
Liver	(15)	(15)
Hepatodiaphragmatic Nodule		1 (7%)
Inflammation, Granulomatous	1 (7%)	1 (7%)
Vacuolization Cytoplasmic, Diffuse	1 (7%)	4 (27%)
Pancreas	(1)	(0)
Stomach, Forestomach	(15)	(15)
Epithelium, Hyperplasia, Diffuse	3 (20%)	4 (27%)
CARDIOVASCULAR SYSTEM		
Heart	(15)	(15)
ENDOCRINE SYSTEM		
Adrenal Cortex	(15)	(15)
Hyperplasia, Focal	2 (13%)	
Hypertrophy, Focal	3 (20%)	2 (13%)
Adrenal Medulla	(15)	(15)
Islets, Pancreatic	(1)	(0)
Pituitary Gland	(15)	(15)
Thyroid Gland	(15)	(15)
GENERAL BODY SYSTEM		
Tissue NOS	(0)	(1)
Cyst		1 (100%)

Test Type: 26-WEEK

Route: GAVAGE

Species/Strain: Mouse/FVB/N

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FVB/N Mouse MALE	0 UG/KG	480 UG/KG
GENITAL SYSTEM		
Epididymis	(15)	(15)
Degeneration	2 (13%)	2 (13%)
Prostate	(15)	(15)
Epithelium, Cytoplasmic Alteration	3 (20%)	15 (100%)
Seminal Vesicle	(15)	(15)
Testes	(15)	(15)
Germinal Epith, Atrophy	2 (13%)	2 (13%)
Interstit Cell, Hyperplasia	2 (13%)	2 (13%)
Rete Testes, Cyst		1 (7%)
HEMATOPOIETIC SYSTEM		
Lymph Node	(13)	(15)
Lymph Node, Mandibular	(14)	(15)
Hyperplasia, Lymphoid	2 (14%)	2 (13%)
Lymph Node, Mesenteric	(15)	(15)
Spleen	(15)	(15)
Hematopoietic Cell Proliferation		1 (7%)
Thymus	(15)	(15)
INTEGUMENTARY SYSTEM		
Mammary Gland	(0)	(5)
Skin	(15)	(15)
MUSCULOSKELETAL SYSTEM		
None		
NERVOUS SYSTEM		
None		
RESPIRATORY SYSTEM		
Lung	(15)	(15)

Test Type: 26-WEEK Route: GAVAGE

Species/Strain: Mouse/FVB/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Transgenic model evaluation (DES)

CAS Number: 56-53-1

Date Report Requested: 10/21/2014 Time Report Requested: 17:34:07 First Dose M/F: NA / NA Lab: BAT

FVB/N Mouse MALE	0 UG/KG	480 UG/KG
Alveolar Epith, Hyperplasia, Focal	2 (13%)	
Inflammation, Chronic Active, Focal	3 (20%)	2 (13%)
Metaplasia, Osseous		1 (7%)
SPECIAL SENSES SYSTEM		
None		
URINARY SYSTEM		
Kidney	(15)	(15)
Casts Protein		1 (7%)
Hydronephrosis		1 (7%)
Infarct	1 (7%)	
Nephropathy	2 (13%)	

END OF MALE DATA

Experiment Number: 97011-20 Test Type: 26-WEEK Route: GAVAGE

Species/Strain: Mouse/FVB/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Transgenic model evaluation (DES)

CAS Number: 56-53-1

Date Report Requested: 10/21/2014 Time Report Requested: 17:34:07 First Dose M/F: NA / NA Lab: BAT

FVB/N Mouse FEMALE	0 UG/KG	480 UG/KG
Disposition Summary		
Animals Initially In Study	15	15
Early Deaths		
Dosing Accident	1	
Natural Death		1
Survivors		
Terminal Sacrifice	14	14
Animals Examined Microscopically	15	15
ALIMENTARY SYSTEM		
Esophagus	(1)	(0)
Muscularis, Inflammation, Chronic	1 (100%)	
Perforation	1 (100%)	
Liver	(15)	(15)
Inflammation, Granulomatous	13 (87%)	9 (60%)
Vacuolization Cytoplasmic, Diffuse	1 (7%)	3 (20%)
Mesentery	(1)	(0)
Stomach, Forestomach	(15)	(15)
Epithelium, Hyperplasia, Diffuse	6 (40%)	4 (27%)
CARDIOVASCULAR SYSTEM		
Heart	(15)	(15)
ENDOCRINE SYSTEM		
Adrenal Cortex	(15)	(15)
Adrenal Medulla	(15)	(15)
Pituitary Gland	(15)	(15)
Cyst	1 (7%)	
Pars Distalis, Hyperplasia	1 (7%)	
Thyroid Gland	(15)	(15)

GENERAL BODY SYSTEM

Test Type: 26-WEEK

Route: GAVAGE

Species/Strain: Mouse/FVB/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Transgenic model evaluation (DES)

CAS Number: 56-53-1

Date Report Requested: 10/21/2014 Time Report Requested: 17:34:07 First Dose M/F: NA / NA Lab: BAT

FVB/N Mouse FEMALE	0 UG/KG	480 UG/KG
None		
GENITAL SYSTEM		
Ovary	(15)	(15)
Corpus Luteum, Hyperplasia	5 (33%)	15 (100%)
Cyst	1 (7%)	3 (20%)
Uterus	(15)	(15)
Endometrium, Hyperplasia, Cystic	6 (40%)	12 (80%)
HEMATOPOIETIC SYSTEM		
Lymph Node	(15)	(14)
Lymph Node, Mandibular	(15)	(15)
Hyperplasia, Lymphoid	2 (13%)	1 (7%)
Lymph Node, Mesenteric	(15)	(15)
Spleen	(15)	(15)
Hematopoietic Cell Proliferation	3 (20%)	
Thymus	(15)	(15)
Atrophy	1 (7%)	2 (13%)
INTEGUMENTARY SYSTEM		
Mammary Gland	(15)	(15)
Skin	(15)	(15)
MUSCULOSKELETAL SYSTEM None		
NERVOUS SYSTEM		
None		
RESPIRATORY SYSTEM		
Lung	(15)	(15)
Alveolar Epith, Hyperplasia, Focal		1 (7%)
Inflammation, Chronic Active, Focal	1 (7%)	3 (20%)

Test Type: 26-WEEK Route: GAVAGE P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Transgenic model evaluation (DES)

CAS Number: 56-53-1

Species/Strain: Mouse/FVB/N

Date Report Requested: 10/21/2014 Time Report Requested: 17:34:07 First Dose M/F: NA / NA Lab: BAT

FVB/N Mouse FEMALE	0 UG/KG	480 UG/KG
Serosa, Inflammation, Chronic Active	1 (7%)	
SPECIAL SENSES SYSTEM		
Eye	(1)	(0)
URINARY SYSTEM		
Kidney	(15)	(15)
Casts Protein		2 (13%)
Nephropathy	3 (20%)	
Renal Tubule, Hyperplasia, Focal	1 (7%)	

** END OF REPORT **