Test Type: 26-WEEK

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

Test Compound: Transgenic model evaluation (DES)

CAS Number: 56-53-1

Route: SKIN APPLICATION

Species/Strain: Mouse/FVB/N

Date Report Requested: 10/22/2014 Time Report Requested: 17:57:52

First Dose M/F: NA / NA

Lab: BAT

C Number: C97011G

Lock Date: 07/19/2001

Cage Range: All

Date Range: All

Reasons For Removal:

Removal Date Range: All

Treatment Groups: All

Study Gender: Both

PWG Approval Date NONE

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) Test Compound: Transgenic model evaluation (DES)

Date Report Requested: 10/22/2014 Time Report Requested: 17:57:52

First Dose M/F: NA / NA

Lab: BAT

CAS Number: 56-53-1

Route: SKIN APPLICATION Species/Strain: Mouse/FVB/N

Test Type: 26-WEEK

FVB/N Mouse MALE	0 UG/KG	480 UG/KG
Disposition Summary		
Animals Initially In Study	15	15
Early Deaths		
Moribund Sacrifice		2
Natural Death		2
Survivors		
Terminal Sacrifice	15	11
Animals Examined Microscopically	15	15
ALIMENTARY SYSTEM		
Liver	(15)	(15)
Basophilic Focus	1 (7%)	
Centrilobular, Midzonal, Hypertrophy		14 (93%)
Clear Cell Focus		1 (7%)
Inflammation, Granulomatous	5 (33%)	10 (67%)
Necrosis, Focal		3 (20%)
Vacuolization Cytoplasmic, Diffuse		1 (7%)
Mesentery	(1)	(0)
Fat, Necrosis	1 (100%)	
Stomach, Forestomach	(15)	(15)
Epithelium, Hyperplasia, Diffuse		3 (20%)
CARDIOVASCULAR SYSTEM		
Blood Vessel	(1)	(3)
Heart	(15)	(15)
ENDOCRINE SYSTEM		
Adrenal Cortex	(15)	(15)
Zona Reticul, Hypertrophy	()	15 (100%)
Zona Reticul, Pigmentation		15 (100%)
Zona Reticul, Syncytial Alteration		15 (100%)

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

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: 10/22/2014 Time Report Requested: 17:57:52

First Dose M/F: NA / NA

Lab: BAT

FVB/N Mouse MALE	0 UG/KG	480 UG/KG

Experiment Number: 97011-18

Test Type: 26-WEEK

Route: SKIN APPLICATION

Species/Strain: Mouse/FVB/N

FVB/N Mouse MALE	0 UG/KG	480 UG/KG
Zona Reticul, Vacuolization Cytoplasmic		15 (100%)
Adrenal Medulla	(15)	(15)
Pituitary Gland	(15)	(15)
Cyst		1 (7%)
Pars Distalis, Cytoplasmic Alteration		15 (100%)
Pars Distalis, Hyperplasia		15 (100%)
Thyroid Gland	(15)	(15)
Hyperplasia, Focal		1 (7%)
GENERAL BODY SYSTEM		
None		
GENITAL SYSTEM		
Coagulating Gland	(15)	(15)
Metaplasia, Squamous		15 (100%)
Epididymis	(15)	(15)
Degeneration	3 (20%)	14 (93%)
Fibrosis		13 (87%)
Preputial Gland	(0)	(7)
Atrophy		7 (100%)
Duct, Hyperplasia		7 (100%)
Prostate	(15)	(15)
Atrophy		13 (87%)
Epithelium, Cytoplasmic Alteration	7 (47%)	
Seminal Vesicle	(15)	(15)
Atrophy		15 (100%)
Testes	(15)	(15)
Germinal Epith, Atrophy	3 (20%)	15 (100%)
Interstit Cell, Hypertrophy		15 (100%)
Interstit Cell, Pigmentation		15 (100%)
Interstit Cell, Syncytial Alteration		14 (93%)

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

Test Type: 26-WEEK

Route: SKIN APPLICATION

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

Time Report Requested: 17:57:52

First Dose M/F: NA / NA

Date Report Requested: 10/22/2014

Lab: BAT

FVB/N Mouse MALE	0 UG/KG	480 UG/KG
Interstit Cell, Vacuolization Cytoplasmic		15 (100%)
Rete Testes, Cyst	1 (7%)	
HEMATOPOIETIC SYSTEM		
Lymph Node	(15)	(15)
Lymph Node, Mandibular	(15)	(15)
Hyperplasia, Lymphoid	2 (13%)	
Lymph Node, Mesenteric	(15)	(15)
Spleen	(15)	(15)
Hematopoietic Cell Proliferation	2 (13%)	8 (53%)
Lymph Follic, Atrophy		1 (7%)
Lymph Follic, Hyperplasia	3 (20%)	3 (20%)
Thymus	(15)	(15)
Atrophy		6 (40%)
INTEGUMENTARY SYSTEM		
Mammary Gland	(0)	(10)
Hyperplasia		10 (100%)
Skin	(15)	(15)
Dermis, SOA, Subcut Tiss, Edema		13 (87%)
Dermis, SOA, Subcut Tiss, Infiltration Cellular, Mononuclear Cl	1 (7%)	12 (80%)
Epidermis, SOA, Hyperplasia	2 (13%)	3 (20%)
Prepuce, Inflammation, Acute		1 (7%)
Prepuce, Inflammation, Suppurative		1 (7%)
SOA, Hyperkeratosis		12 (80%)
Skin, Control	(0)	(15)
		15 (100%)

NERVOUS SYSTEM

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

Test Type: 26-WEEK

Cyst

Route: SKIN APPLICATION

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

First Dose M/F: NA / NA

Date Report Requested: 10/22/2014

Time Report Requested: 17:57:52

Lab: BAT

FVB/N Mouse MALE	0 UG/KG	480 UG/KG
None		
RESPIRATORY SYSTEM		
Lung	(15)	(15)
Inflammation, Chronic, Focal	4 (27%)	5 (33%)
SPECIAL SENSES SYSTEM		
None		
URINARY SYSTEM		
Kidney	(15)	(15)
Casts Protein		1 (7%)
Hydronephrosis		6 (40%)
Inflammation, Chronic, Focal	1 (7%)	
Nephropathy	1 (7%)	
Renal Tubule, Cyst		1 (7%)
Renal Tubule, Hyperplasia, Focal		1 (7%)
Urinary Bladder	(0)	(3)

^{***}END OF MALE DATA***

3 (100%)

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: 10/22/2014 Time Report Requested: 17:57:52

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		
Natural Death	1	
Survivors		
Terminal Sacrifice	14	15
Animals Examined Microscopically	15	15
ALIMENTARY SYSTEM		
Liver	(15)	(15)
Centrilobular, Midzonal, Hypertrophy		13 (87%)
Hematopoietic Cell Proliferation	4 (27%)	5 (33%)
Inflammation, Granulomatous	12 (80%)	14 (93%)
Vacuolization Cytoplasmic, Diffuse	1 (7%)	2 (13%)
Stomach, Forestomach	(15)	(15)
Epithelium, Hyperplasia, Diffuse	4 (27%)	3 (20%)
CARDIOVASCULAR SYSTEM		
Heart	(15)	(15)
ENDOCRINE SYSTEM		
Adrenal Cortex	(15)	(15)
Zona Reticul, Hypertrophy	15 (100%)	15 (100%)
Zona Reticul, Pigmentation	15 (100%)	15 (100%)
Zona Reticul, Syncytial Alteration	15 (100%)	15 (100%)
Zona Reticul, Vacuolization Cytoplasmic	15 (100%)	15 (100%)
Adrenal Medulla	(15)	(15)
Pituitary Gland	(15)	(15)
Cyst	3 (20%)	
Pars Distalis, Cytoplasmic Alteration		15 (100%)
Pars Distalis, Degeneration, Focal	1 (7%)	

Experiment Number: 97011-18

Test Type: 26-WEEK

Route: SKIN APPLICATION

Species/Strain: Mouse/FVB/N

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

Test Compound: Transgenic model evaluation (DES)

CAS Number: 56-53-1

Route: SKIN APPLICATION
Species/Strain: Mouse/FVB/N

Test Type: 26-WEEK

Date Report Requested: 10/22/2014 Time Report Requested: 17:57:52 First Dose M/F: NA / NA

Lab: BAT

FVB/N Mouse FEMALE	0 UG/KG	480 UG/KG
Pars Distalis, Hyperplasia		15 (100%)
Thyroid Gland	(15)	(15)
GENERAL BODY SYSTEM		
None		
GENITAL SYSTEM		
Clitoral Gland	(0)	(1)
Inflammation, Suppurative		1 (100%)
Ovary	(15)	(15)
Corpus Luteum, Atrophy	1 (7%)	15 (100%)
Cyst	2 (13%)	4 (27%)
Oviduct	(15)	(15)
Epithelium, Hyperplasia		15 (100%)
Uterus	(15)	(15)
Endometrium, Hyperplasia, Cystic	10 (67%)	15 (100%)
HEMATOPOIETIC SYSTEM		
Lymph Node	(13)	(13)
Lymph Node, Mandibular	(15)	(14)
Hyperplasia, Lymphoid	1 (7%)	4 (29%)
Lymph Node, Mesenteric	(15)	(15)
Spleen	(15)	(15)
Hematopoietic Cell Proliferation	1 (7%)	10 (67%)
Lymph Follic, Atrophy	1 (7%)	
Thymus	(15)	(14)
Atrophy	1 (7%)	2 (14%)
INTEGUMENTARY SYSTEM		
Mammary Gland	(15)	(15)
Hyperplasia		15 (100%)
Skin	(14)	(15)

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

Test Type: 26-WEEK

Route: SKIN APPLICATION

Species/Strain: Mouse/FVB/N

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Date Report Requested: 10/22/2014

First Dose M/F: NA / NA

Lab: BAT

FVB/N Mouse FEMALE	0 UG/KG	480 UG/KG	
Dermis, SOA, Subcut Tiss, Edema		14 (93%)	
Dermis, SOA, Subcut Tiss, Infiltration Cellular, Mononuclear Cl		3 (20%)	
SOA, Hyperkeratosis		15 (100%)	
Skin, Control	(1)	(15)	
Epidermis, Hyperplasia	1 (100%)		
Hyperkeratosis		15 (100%)	
Parakeratosis		1 (7%)	
MUSCULOSKELETAL SYSTEM None			
NERVOUS SYSTEM			
None			
RESPIRATORY SYSTEM			
Lung	(15)	(15)	
Alveolar Epith, Hyperplasia, Focal		1 (7%)	
Hyperplasia, Lymphoid, Focal		1 (7%)	
Inflammation, Chronic, Focal	5 (33%)	4 (27%)	
SPECIAL SENSES SYSTEM None			
URINARY SYSTEM			
Kidney	(15)	(15)	
Casts Protein	5 (33%)	8 (53%)	
Hydronephrosis		1 (7%)	
Infarct	1 (7%)		
Inflammation, Chronic Active	1 (7%)		
Nephropathy	1 (7%)	3 (20%)	
Renal Tubule, Cyst		1 (7%)	
Renal Tubule, Hyperplasia, Focal	2 (13%)	3 (20%)	

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

Test Type: 26-WEEK

Route: SKIN APPLICATION

Species/Strain: Mouse/FVB/N

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Date Report Requested: 10/22/2014 Time Report Requested: 17:57:53

First Dose M/F: NA / NA

Lab: BAT

FVB/N Mouse FEMALE

0 UG/KG

480 UG/KG

** END OF REPORT **