

Experiment Number: 97011-18
Test Type: 26-WEEK
Route: SKIN APPLICATION
Species/Strain: Mouse/FVB/N

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Test Compound: Transgenic model evaluation (DES)

CAS Number: 56-53-1

Date Report Requested: 10/22/2014

Time Report Requested: 17:57:30

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:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Both
PWG Approval Date	NONE

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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	
Centrilobular, Midzonal, Hypertrophy		14 [1.9]
Clear Cell Focus		1
Inflammation, Granulomatous	5 [1.0]	10 [1.0]
Necrosis, Focal		3 [2.0]
Vacuolization Cytoplasmic, Diffuse		1 [4.0]
Mesentery	(1)	(0)
Fat, Necrosis	1 [2.0]	
Stomach, Forestomach	(15)	(15)
Epithelium, Hyperplasia, Diffuse		3 [1.0]
CARDIOVASCULAR SYSTEM		
Blood Vessel	(1)	(3)
Heart	(15)	(15)
ENDOCRINE SYSTEM		
Adrenal Cortex	(15)	(15)
Zona Reticul, Hypertrophy		15 [3.1]
Zona Reticul, Pigmentation		15 [3.1]

a - Number of animals examined microscopically at site and number of animals with lesion
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Zona Reticul, Syncytial Alteration		15 [3.1]
Zona Reticul, Vacuolization Cytoplasmic		15 [3.1]
Adrenal Medulla	(15)	(15)
Pituitary Gland	(15)	(15)
Cyst		1 [1.0]
Pars Distalis, Cytoplasmic Alteration		15 [2.8]
Pars Distalis, Hyperplasia		15 [2.8]
Thyroid Gland	(15)	(15)
Hyperplasia, Focal		1 [1.0]

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Coagulating Gland	(15)	(15)
Metaplasia, Squamous		15 [4.0]
Epididymis	(15)	(15)
Degeneration	3 [3.0]	14 [2.2]
Fibrosis		13 [1.0]
Preputial Gland	(0)	(7)
Atrophy		7 [2.1]
Duct, Hyperplasia		7 [3.0]
Prostate	(15)	(15)
Atrophy		13 [3.1]
Epithelium, Cytoplasmic Alteration	7 [1.0]	
Seminal Vesicle	(15)	(15)
Atrophy		15 [4.0]
Testes	(15)	(15)
Germinal Epith, Atrophy	3 [1.7]	15 [2.6]
Interstitial Cell, Hypertrophy		15 [2.6]

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Interstit Cell, Pigmentation		15 [2.6]
Interstit Cell, Syncytial Alteration		14 [2.3]
Interstit Cell, Vacuolization Cytoplasmic		15 [2.6]
Rete Testes, Cyst	1 [3.0]	
HEMATOPOIETIC SYSTEM		
Lymph Node	(15)	(15)
Lymph Node, Mandibular	(15)	(15)
Hyperplasia, Lymphoid	2 [3.0]	
Lymph Node, Mesenteric	(15)	(15)
Spleen	(15)	(15)
Hematopoietic Cell Proliferation	2 [1.0]	8 [1.4]
Lymph Follic, Atrophy		1 [3.0]
Lymph Follic, Hyperplasia	3 [1.3]	3 [1.0]
Thymus	(15)	(15)
Atrophy		6 [2.3]
INTEGUMENTARY SYSTEM		
Mammary Gland	(0)	(10)
Hyperplasia		10 [2.1]
Skin	(15)	(15)
Dermis, SOA, Subcut Tiss, Edema		13 [1.1]
Dermis, SOA, Subcut Tiss, Infiltration Cellular, Mononuclear Cl	1 [1.0]	12 [1.0]
Epidermis, SOA, Hyperplasia	2 [1.0]	3 [1.0]
Prepuce, Inflammation, Acute		1 [4.0]
Prepuce, Inflammation, Suppurative		1 [4.0]
SOA, Hyperkeratosis		12 [1.0]
Skin, Control	(0)	(15)
Hyperkeratosis		15 [1.0]

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Lab: BAT

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<hr/>		
MUSCULOSKELETAL SYSTEM		
None		
<hr/>		
NERVOUS SYSTEM		
None		
<hr/>		
RESPIRATORY SYSTEM		
Lung	(15)	(15)
Inflammation, Chronic, Focal	4 [1.0]	5 [1.0]
<hr/>		
SPECIAL SENSES SYSTEM		
None		
<hr/>		
URINARY SYSTEM		
Kidney	(15)	(15)
Casts Protein		1 [1.0]
Hydronephrosis		6 [3.0]
Inflammation, Chronic, Focal	1 [1.0]	
Nephropathy	1 [1.0]	
Renal Tubule, Cyst		1 [1.0]
Renal Tubule, Hyperplasia, Focal		1 [1.0]
Urinary Bladder	(0)	(3)
Cyst		3 [4.0]

END OF MALE DATA

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 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 [1.0]
Hematopoietic Cell Proliferation	4 [1.0]	5 [1.0]
Inflammation, Granulomatous	12 [1.0]	14 [1.0]
Vacuolization Cytoplasmic, Diffuse	1 [2.0]	2 [3.0]
Stomach, Forestomach	(15)	(15)
Epithelium, Hyperplasia, Diffuse	4 [1.3]	3 [1.7]
CARDIOVASCULAR SYSTEM		
Heart	(15)	(15)
ENDOCRINE SYSTEM		
Adrenal Cortex	(15)	(15)
Zona Reticul, Hypertrophy	15 [1.5]	15 [2.8]
Zona Reticul, Pigmentation	15 [1.5]	15 [2.8]
Zona Reticul, Syncytial Alteration	15 [1.5]	15 [2.8]
Zona Reticul, Vacuolization Cytoplasmic	15 [1.5]	15 [2.8]
Adrenal Medulla	(15)	(15)
Pituitary Gland	(15)	(15)
Cyst	3 [1.0]	
Pars Distalis, Cytoplasmic Alteration		15 [2.3]

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Lab: BAT

FVB/N Mouse FEMALE	0 UG/KG	480 UG/KG
Pars Distalis, Degeneration, Focal	1 [1.0]	
Pars Distalis, Hyperplasia		15 [2.3]
Thyroid Gland	(15)	(15)
GENERAL BODY SYSTEM		
None		
GENITAL SYSTEM		
Clitoral Gland	(0)	(1)
Inflammation, Suppurative		1 [3.0]
Ovary	(15)	(15)
Corpus Luteum, Atrophy	1 [2.0]	15 [3.8]
Cyst	2 [1.5]	4 [1.8]
Oviduct	(15)	(15)
Epithelium, Hyperplasia		15 [1.3]
Uterus	(15)	(15)
Endometrium, Hyperplasia, Cystic	10 [1.1]	15 [1.9]
HEMATOPOIETIC SYSTEM		
Lymph Node	(13)	(13)
Lymph Node, Mandibular	(15)	(14)
Hyperplasia, Lymphoid	1 [3.0]	4 [2.5]
Lymph Node, Mesenteric	(15)	(15)
Spleen	(15)	(15)
Hematopoietic Cell Proliferation	1 [1.0]	10 [1.1]
Lymph Follic, Atrophy	1 [2.0]	
Thymus	(15)	(14)
Atrophy	1 [3.0]	2 [4.0]
INTEGUMENTARY SYSTEM		
Mammary Gland	(15)	(15)

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Lab: BAT

FVB/N Mouse FEMALE	0 UG/KG	480 UG/KG
Hyperplasia		15 [1.4]
Skin	(14)	(15)
Dermis, SOA, Subcut Tiss, Edema		14 [1.0]
Dermis, SOA, Subcut Tiss, Infiltration Cellular, Mononuclear Cl		3 [1.0]
SOA, Hyperkeratosis		15 [1.1]
Skin, Control	(1)	(15)
Epidermis, Hyperplasia	1 [1.0]	
Hyperkeratosis		15 [1.0]
Parakeratosis		1 [1.0]
<hr/>		
MUSCULOSKELETAL SYSTEM		
None		
<hr/>		
NERVOUS SYSTEM		
None		
<hr/>		
RESPIRATORY SYSTEM		
Lung	(15)	(15)
Alveolar Epith, Hyperplasia, Focal		1 [1.0]
Hyperplasia, Lymphoid, Focal		1 [1.0]
Inflammation, Chronic, Focal	5 [1.2]	4 [1.0]
<hr/>		
SPECIAL SENSES SYSTEM		
None		
<hr/>		
URINARY SYSTEM		
Kidney	(15)	(15)
Casts Protein	5 [1.0]	8 [1.0]
Hydronephrosis		1 [2.0]
Infarct	1 [2.0]	
Inflammation, Chronic Active	1 [3.0]	

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First Dose M/F: NA / NA

Lab: BAT

FVB/N Mouse FEMALE	0 UG/KG	480 UG/KG
Nephropathy	1 [1.0]	3 [1.0]
Renal Tubule, Cyst		1 [1.0]
Renal Tubule, Hyperplasia, Focal	2 [1.0]	3 [1.0]

**** END OF REPORT ****

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