

TDMS No. 20307 - 04

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E
Super)

CAS Number: 54464-57-2

Date Report Requested: 07/27/2011

Time Report Requested: 12:17:04

First Dose M/F: 12/14/06 / 12/15/06

Lab: MBA

F1_M3

C Number: C20307
Lock Date: 12/28/2009
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.4.2.1_003
PWG Approval Date: NONE

B6C3F1 MICE MALE	untreated	vehicle	6.25%	12.5 %	25 %	50 %
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Disposition Summary

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10

ALIMENTARY SYSTEM

Esophagus	(9)	(10)	(0)	(0)	(0)	(0)
Gallbladder	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Large, Cecum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Large, Colon	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Large, Rectum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Small, Duodenum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Small, Ileum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Small, Jejunum	(10)	(10)	(0)	(0)	(0)	(0)
Liver	(10)	(10)	(10)	(10)	(9)	(10)
Centrilobular, Hypertrophy		1 (10%)		2 (20%)	3 (33%)	
Oral Mucosa	(10)	(10)	(0)	(0)	(0)	(0)
Pancreas	(10)	(10)	(0)	(0)	(0)	(0)
Salivary Glands	(10)	(10)	(0)	(0)	(0)	(0)
Stomach, Forestomach	(10)	(10)	(0)	(0)	(0)	(0)
Stomach, Glandular	(10)	(10)	(0)	(0)	(0)	(0)
Tongue	(10)	(10)	(0)	(0)	(0)	(0)

CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(10)	(0)	(0)	(0)	(0)
Heart	(10)	(10)	(0)	(0)	(0)	(0)

ENDOCRINE SYSTEM

Adrenal Cortex	(10)	(10)	(0)	(0)	(0)	(0)
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a - Number of animals examined microscopically at site and number of animals with lesion

B6C3F1 MICE MALE	untreated	vehicle	6.25%	12.5 %	25 %	50 %
Adrenal Medulla	(10)	(10)	(0)	(0)	(0)	(0)
Parathyroid Gland	(9)	(10)	(0)	(0)	(0)	(0)
Cyst	1 (11%)	2 (20%)				
Pituitary Gland	(10)	(9)	(0)	(0)	(0)	(0)
Thyroid Gland	(10)	(10)	(0)	(0)	(0)	(0)
Follicle, Degeneration	1 (10%)					

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(10)	(10)	(0)	(0)	(0)	(0)
Preputial Gland	(10)	(10)	(0)	(0)	(0)	(0)
Prostate	(10)	(10)	(0)	(0)	(0)	(0)
Seminal Vesicle	(10)	(10)	(0)	(0)	(0)	(0)
Testes	(10)	(10)	(0)	(0)	(0)	(0)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Lymph Node, Mandibular	(9)	(10)	(0)	(0)	(0)	(0)
Lymph Node, Mesenteric	(10)	(10)	(0)	(0)	(0)	(0)
Spleen	(10)	(10)	(10)	(10)	(9)	(10)
Thymus	(10)	(10)	(0)	(0)	(0)	(0)

INTEGUMENTARY SYSTEM

Mammary Gland	(4)	(4)	(0)	(0)	(0)	(0)
Skin	(10)	(10)	(10)	(10)	(9)	(10)
Control, Fibrosis					1 (11%)	2 (20%)
Control, Hyperkeratosis						2 (20%)

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

B6C3F1 MICE MALE	untreated	vehicle	6.25%	12.5 %	25 %	50 %
Control, Hyperplasia				2 (20%)	4 (44%)	3 (30%)
Control, Inflammation, Neutrophil						
Control, Inflammation, Chronic Active				2 (20%)	4 (44%)	2 (20%)
Control, Epidermis, Inflammation, Suppurative						1 (10%)
Control, Hair Follicle, Hyperplasia				1 (10%)		1 (10%)
Skin, Site Of Application	(10)	(10)	(10)	(10)	(10)	(9)
Fibrosis			4 (40%)	3 (30%)	8 (80%)	8 (89%)
Hyperkeratosis			2 (20%)	5 (50%)	5 (50%)	8 (89%)
Hyperplasia			9 (90%)	10 (100%)	9 (90%)	9 (100%)
Inflammation, Chronic Active			7 (70%)	10 (100%)	9 (90%)	9 (100%)
Epidermis, Inflammation, Suppurative					1 (10%)	1 (11%)
Hair Follicle, Hyperplasia			3 (30%)	2 (20%)	3 (30%)	7 (78%)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(10)	(0)	(0)	(0)	(0)
Skeletal Muscle	(0)	(1)	(0)	(0)	(0)	(0)
NERVOUS SYSTEM						
Brain	(10)	(10)	(0)	(0)	(0)	(0)
RESPIRATORY SYSTEM						
Larynx	(10)	(10)	(0)	(0)	(0)	(0)
Lung	(10)	(10)	(0)	(0)	(0)	(0)
Nose	(10)	(10)	(0)	(0)	(0)	(0)
Trachea	(10)	(10)	(0)	(0)	(0)	(0)
SPECIAL SENSES SYSTEM						
Eye	(10)	(10)	(0)	(0)	(0)	(0)
Retina, Dysplasia		1 (10%)				

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P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super)

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Lab: MBA

B6C3F1 MICE MALE	untreated	vehicle	6.25%	12.5 %	25 %	50 %
Retrobulbar, Inflammation, Neutrophil	1 (10%)					
Harderian Gland	(10)	(10)	(0)	(0)	(0)	(0)
Inflammation, Neutrophil		2 (20%)				
Inflammation, Chronic						
URINARY SYSTEM						
Kidney	(10)	(10)	(0)	(0)	(0)	(0)
Inflammation, Chronic		1 (10%)				
Urinary Bladder	(10)	(10)	(0)	(0)	(0)	(0)

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B6C3F1 MICE MALE

100 %

Disposition Summary

Animals Initially In Study	10
Early Deaths	
Survivors	
Terminal Sacrifice	10
Animals Examined Microscopically	10

ALIMENTARY SYSTEM

Esophagus	(9)
Gallbladder	(10)
Intestine Large, Cecum	(10)
Intestine Large, Colon	(10)
Intestine Large, Rectum	(10)
Intestine Small, Duodenum	(10)
Intestine Small, Ileum	(10)
Intestine Small, Jejunum	(10)
Liver	(10)
Centrilobular, Hypertrophy	4 (40%)
Oral Mucosa	(10)
Pancreas	(10)
Salivary Glands	(10)
Stomach, Forestomach	(10)
Stomach, Glandular	(10)
Tongue	(10)

CARDIOVASCULAR SYSTEM

Blood Vessel	(10)
Heart	(10)

ENDOCRINE SYSTEM

Adrenal Cortex	(10)
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B6C3F1 MICE MALE

100 %

Adrenal Medulla	(10)
Parathyroid Gland	(10)
Cyst	
Pituitary Gland	(10)
Thyroid Gland	(10)
Follicle, Degeneration	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(10)
Preputial Gland	(10)
Prostate	(10)
Seminal Vesicle	(10)
Testes	(10)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)
Lymph Node, Mandibular	(9)
Lymph Node, Mesenteric	(10)
Spleen	(10)
Thymus	(10)

INTEGUMENTARY SYSTEM

Mammary Gland	(4)
Skin	(10)
Control, Fibrosis	5 (50%)
Control, Hyperkeratosis	5 (50%)

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B6C3F1 MICE MALE

100 %

Control, Hyperplasia	8 (80%)
Control, Inflammation, Neutrophil	1 (10%)
Control, Inflammation, Chronic Active	8 (80%)
Control, Epidermis, Inflammation, Suppurative	4 (40%)
Control, Hair Follicle, Hyperplasia	5 (50%)
Skin, Site Of Application	(10)
Fibrosis	10 (100%)
Hyperkeratosis	10 (100%)
Hyperplasia	10 (100%)
Inflammation, Chronic Active	10 (100%)
Epidermis, Inflammation, Suppurative	5 (50%)
Hair Follicle, Hyperplasia	8 (80%)

MUSCULOSKELETAL SYSTEM

Bone	(10)
Skeletal Muscle	(0)

NERVOUS SYSTEM

Brain	(10)
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RESPIRATORY SYSTEM

Larynx	(10)
Lung	(10)
Nose	(10)
Trachea	(10)

SPECIAL SENSES SYSTEM

Eye	(10)
Retina, Dysplasia	

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B6C3F1 MICE MALE

100 %

Retrobulbar, Inflammation, Neutrophil	
Harderian Gland	(10)
Inflammation, Neutrophil	1 (10%)
Inflammation, Chronic	1 (10%)

URINARY SYSTEM

Kidney	(10)
Inflammation, Chronic	
Urinary Bladder	(10)

*** END OF MALE ***

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

B6C3F1 MICE FEMALE	untreated	vehicle	6.25 %	12.5 %	25 %	50 %
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Disposition Summary

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10

ALIMENTARY SYSTEM

Esophagus	(10)	(10)	(0)	(0)	(0)	(0)
Gallbladder	(10)	(9)	(0)	(0)	(0)	(0)
Intestine Large, Cecum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Large, Colon	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Large, Rectum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Small, Duodenum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Small, Ileum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Small, Jejunum	(10)	(10)	(0)	(0)	(0)	(0)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Oral Mucosa	(10)	(10)	(0)	(0)	(0)	(0)
Pancreas	(10)	(10)	(0)	(0)	(0)	(0)
Salivary Glands	(10)	(10)	(0)	(0)	(0)	(0)
Stomach, Forestomach	(10)	(10)	(0)	(0)	(0)	(0)
Stomach, Glandular	(10)	(10)	(0)	(0)	(0)	(0)
Tongue	(10)	(10)	(0)	(0)	(0)	(0)

CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(10)	(0)	(0)	(0)	(0)
Heart	(10)	(10)	(10)	(10)	(10)	(9)

ENDOCRINE SYSTEM

Adrenal Cortex	(10)	(10)	(0)	(0)	(0)	(0)
Adrenal Medulla	(10)	(10)	(0)	(0)	(0)	(0)

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

B6C3F1 MICE FEMALE	untreated	vehicle	6.25 %	12.5 %	25 %	50 %
Parathyroid Gland Cyst	(9)	(7)	(0)	(0)	(0)	(0)
Pituitary Gland	(10)	(10)	(0)	(0)	(0)	(0)
Thyroid Gland	(10)	(10)	(0)	(0)	(0)	(0)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(9)	(6)	(0)	(0)	(0)	(0)
Ovary	(10)	(10)	(0)	(0)	(0)	(0)
Uterus	(10)	(10)	(0)	(0)	(0)	(0)
Vagina	(10)	(10)	(0)	(0)	(0)	(0)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Lymph Node	(0)	(0)	(0)	(0)	(0)	(0)
Lymph Node, Mandibular	(10)	(10)	(0)	(0)	(0)	(0)
Lymph Node, Mesenteric	(10)	(10)	(0)	(0)	(0)	(0)
Spleen	(10)	(10)	(10)	(10)	(10)	(8)
Thymus Atrophy	(10)	(10)	(10)	(10)	(10)	(8)

INTEGUMENTARY SYSTEM

Mammary Gland	(10)	(10)	(0)	(0)	(0)	(0)
Skin	(10)	(10)	(10)	(10)	(10)	(8)
Control, Fibrosis				3 (30%)		
Control, Hyperkeratosis				1 (10%)		
Control, Hyperplasia			4 (40%)	3 (30%)	2 (20%)	3 (38%)

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

B6C3F1 MICE FEMALE	untreated	vehicle	6.25 %	12.5 %	25 %	50 %
Control, Inflammation, Chronic Active			4 (40%)	4 (40%)	2 (20%)	3 (38%)
Control, Ulcer						
Control, Epidermis, Inflammation, Suppurative					1 (10%)	
Control, Hair Follicle, Hyperplasia					1 (10%)	
Skin, Site Of Application	(10)	(10)	(10)	(10)	(10)	(6)
Fibrosis			2 (20%)	10 (100%)	10 (100%)	4 (67%)
Hyperkeratosis			5 (50%)	5 (50%)	10 (100%)	6 (100%)
Hyperplasia			10 (100%)	10 (100%)	10 (100%)	6 (100%)
Inflammation, Chronic Active			10 (100%)	10 (100%)	10 (100%)	6 (100%)
Ulcer		1 (10%)				1 (17%)
Epidermis, Inflammation, Suppurative				1 (10%)	4 (40%)	4 (67%)
Hair Follicle, Hyperplasia			3 (30%)		4 (40%)	3 (50%)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(10)	(0)	(0)	(0)	(0)
NERVOUS SYSTEM						
Brain	(10)	(10)	(0)	(0)	(0)	(0)
RESPIRATORY SYSTEM						
Larynx	(10)	(10)	(0)	(0)	(0)	(0)
Lung	(10)	(10)	(0)	(0)	(0)	(0)
Nose	(10)	(10)	(0)	(0)	(0)	(0)
Trachea	(10)	(10)	(0)	(0)	(0)	(0)
SPECIAL SENSES SYSTEM						
Eye	(10)	(10)	(0)	(0)	(0)	(0)
Retrobulbar, Inflammation, Neutrophil						
Harderian Gland	(10)	(10)	(0)	(0)	(0)	(0)

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B6C3F1 MICE FEMALE	untreated	vehicle	6.25 %	12.5 %	25 %	50 %
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URINARY SYSTEM

Kidney	(10)	(10)	(0)	(0)	(0)	(0)
Nephropathy		1 (10%)				
Urinary Bladder	(9)	(10)	(0)	(0)	(0)	(0)

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Lab: MBA

B6C3F1 MICE FEMALE 100 %

Disposition Summary

Animals Initially In Study	10
Early Deaths	
Survivors	
Terminal Sacrifice	10
Animals Examined Microscopically	10

ALIMENTARY SYSTEM

Esophagus	(10)
Gallbladder	(10)
Intestine Large, Cecum	(10)
Intestine Large, Colon	(10)
Intestine Large, Rectum	(10)
Intestine Small, Duodenum	(10)
Intestine Small, Ileum	(10)
Intestine Small, Jejunum	(10)
Liver	(10)
Oral Mucosa	(10)
Pancreas	(10)
Salivary Glands	(10)
Stomach, Forestomach	(10)
Stomach, Glandular	(10)
Tongue	(10)

CARDIOVASCULAR SYSTEM

Blood Vessel	(10)
Heart	(10)

ENDOCRINE SYSTEM

Adrenal Cortex	(10)
Adrenal Medulla	(10)

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B6C3F1 MICE FEMALE

100 %

Parathyroid Gland	(8)
Cyst	1 (13%)
Pituitary Gland	(9)
Thyroid Gland	(10)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(10)
Ovary	(10)
Uterus	(10)
Vagina	(10)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)
Lymph Node	(1)
Lymph Node, Mandibular	(10)
Lymph Node, Mesenteric	(10)
Spleen	(10)
Thymus	(10)
Atrophy	2 (20%)

INTEGUMENTARY SYSTEM

Mammary Gland	(10)
Skin	(10)
Control, Fibrosis	6 (60%)
Control, Hyperkeratosis	7 (70%)
Control, Hyperplasia	10 (100%)

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B6C3F1 MICE FEMALE

100 %

Control, Inflammation, Chronic Active	8 (80%)
Control, Ulcer	1 (10%)
Control, Epidermis, Inflammation, Suppurative	8 (80%)
Control, Hair Follicle, Hyperplasia	3 (30%)
Skin, Site Of Application	(10)
Fibrosis	9 (90%)
Hyperkeratosis	10 (100%)
Hyperplasia	10 (100%)
Inflammation, Chronic Active	10 (100%)
Ulcer	
Epidermis, Inflammation, Suppurative	7 (70%)
Hair Follicle, Hyperplasia	10 (100%)

MUSCULOSKELETAL SYSTEM

Bone (10)

NERVOUS SYSTEM

Brain (10)

RESPIRATORY SYSTEM

Larynx (10)
Lung (10)
Nose (10)
Trachea (10)

SPECIAL SENSES SYSTEM

Eye (10)
Retrolbulbar, Inflammation, Neutrophil 1 (10%)
Harderian Gland (10)

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

TDMS No. 20307 - 04

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super)

CAS Number: 54464-57-2

Date Report Requested: 07/27/2011

Time Report Requested: 12:17:04

First Dose M/F: 12/14/06 / 12/15/06

Lab: MBA

B6C3F1 MICE FEMALE

100 %

URINARY SYSTEM

Kidney (10)

 Nephropathy

Urinary Bladder (10)

*** END OF REPORT ***

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