

Experiment Number: 55323-01
Test Type: 90-DAY
Route: SKIN APPLICATION
Species/Strain: Rat/F 344/N

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

Test Compound: Lauric acid diethanolamine condensate

CAS Number: 120-40-1

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:50

First Dose M/F: NA / NA

Lab: BAT

C Number: C55323B
Lock Date: 08/11/1992
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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F 344/N Rat MALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
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)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Parasite Metazoan	1					
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(0)	(0)	(2)	(1)	(10)
Hepatodiaphragmatic Nodule				2	1	
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	4 [1.3]					3 [1.0]
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Hyperplasia	1 [1.0]					

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

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Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM						
Tissue NOS	(3)	(0)	(0)	(0)	(0)	(3)
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	8 [1.4]					2 [1.0]
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	2 [1.5]					2 [2.0]
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(0)	(0)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(7)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Epidermis, SOA, Hyperplasia		2 [1.0]	8 [1.0]	10 [2.1]	10 [2.7]	10 [3.0]
SOA, Inflammation, Chronic Active				1 [2.0]	10 [2.2]	10 [3.2]
SOA, Parakeratosis				2 [2.5]	10 [2.8]	10 [3.9]

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Lab: BAT

F 344/N Rat MALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
SOA, Sebaceous GI, Hyperplasia			8 [1.0]	10 [2.1]	10 [2.4]	10 [3.0]
SOA, Ulcer				1 [1.0]	10 [2.9]	10 [3.4]
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic	2 [2.0]					1 [2.0]
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(9)	(10)	(10)
Mineralization						1 [1.0]
Renal Tubule, Regeneration	10 [1.0]	10 [1.0]	10 [1.0]	9 [1.0]	10 [1.0]	8 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

END OF MALE DATA

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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)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Parasite Metazoan	1					
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(0)	(2)	(1)	(1)	(10)
Basophilic Focus	1					
Hepatodiaphragmatic Nodule			2	1	1	2
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Coron Artery, Inflammation, Chronic	1 [2.0]					
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)

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Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pars Distalis, Cyst						1 [1.0]
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM						
Tissue NOS	(0)	(0)	(0)	(0)	(0)	(1)
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	10 [1.0]					10 [1.0]
Ovary	(10)	(0)	(1)	(0)	(0)	(10)
Periovarn Tiss, Cyst	3 [1.7]		1 [2.0]			1 [1.0]
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(9)	(10)	(10)	(10)	(10)	(10)
Epidermis, SOA, Hyperplasia		6 [1.0]	7 [1.0]	9 [1.8]	10 [2.4]	10 [3.0]
SOA, Hyperkeratosis				1 [2.0]	2 [2.0]	
SOA, Inflammation, Chronic Active					9 [2.0]	10 [3.0]
SOA, Parakeratosis					7 [2.7]	10 [4.0]

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F 344/N Rat FEMALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
SOA, Sebaceous GI, Hyperplasia			7 [1.0]	8 [1.9]	9 [2.1]	10 [3.0]
SOA, Ulcer					5 [2.8]	10 [2.9]
Skin, Control	(1)	(0)	(0)	(0)	(0)	(0)
Nipple, Cyst Epithelial Inclusion	1					
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Foreign Body, Chronic Inflammation, Chronic Active	4 [2.0]					1 [1.0] 4 [1.5]
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Mineralization	10 [1.1]	10 [1.0]	10 [1.0]	10 [1.0]	10 [1.0]	10 [1.0]
Renal Tubule, Regeneration	3 [1.0]	1 [1.0]	1 [1.0]	2 [1.0]	6 [1.0]	10 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

**** END OF REPORT ****

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)