

Experiment Number: 91014-01
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: Oleic acid diethanolamine condensate
CAS Number: 93-83-4

Date Report Requested: 10/19/2014
Time Report Requested: 08:00:28
First Dose M/F: NA / NA
Lab: BAT

C Number:	C91014
Lock Date:	02/17/1993
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)
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)	(1)	(0)	(0)	(0)	(10)
Centrilobular, Vacuolization Cytoplasmic	6 [1.0]					7 [1.0]
Hepatodiaphragmatic Nodule		1				
Inflammation, Granulomatous	4 [1.0]					
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Regeneration	1 [1.0]					
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						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)

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)

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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
Myocardium, Cardiomyopathy	6 [1.2]					8 [1.0]
Myocardium, Hemorrhage	1 [1.0]					
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(8)	(0)	(0)	(0)	(0)	(7)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ultimobranchial Cyst	2 [1.0]					2 [1.0]
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	6 [1.2]					4 [1.0]
Inflammation, Granulomatous						1 [2.0]
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Suppurative	3 [1.3]					
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)

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INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Dermis, SOA, Inflammation, Chronic Active			2 [1.0]	6 [1.2]	9 [1.0]	10 [1.1]
Epidermis, SOA, Inflammation, Suppurative				1 [2.0]	3 [1.0]	5 [1.4]
Epidermis, SOA, Ulcer					1 [2.0]	
SOA, Hyperplasia			7 [1.0]	8 [1.8]	9 [2.0]	10 [2.2]
SOA, Parakeratosis				2 [1.5]	9 [1.7]	10 [1.8]
SOA, Sebaceous Gl, Hypertrophy				2 [1.5]	8 [1.6]	10 [2.0]
SOA, Ulcer					2 [2.0]	
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)
Alveolus, Inflammation, Chronic Active	3 [1.0]					
Perivascular, Inflammation, Chronic Active	4 [2.0]					3 [2.0]
Serosa, Fibrosis						1 [1.0]
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	1 [1.0]					
Renal Tubule, Regeneration	6 [1.0]					5 [1.0]

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Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: Rat/F 344/N

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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
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

END OF MALE DATA

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

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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)
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)	(1)	(0)	(0)	(0)	(10)
Hepatodiaphragmatic Nodule	3	1				2
Inflammation, Chronic Active						1 [1.0]
Inflammation, Granulomatous	3 [1.0]					4 [1.0]
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Atrophy	1 [1.0]					
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						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Myocardium, Cardiomyopathy	2 [1.0]					1 [1.0]

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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
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(1)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(9)	(0)	(0)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ultimobranchial Cyst	3 [1.3]					2 [1.0]
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	7 [1.1]					3 [1.0]
Ovary	(10)	(1)	(1)	(2)	(0)	(10)
Follicle, Cyst		1 [1.0]				
Mineralization						1 [1.0]
Periovarn Tiss, Cyst	4 [1.3]		1 [1.0]	2 [2.0]		1 [3.0]
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Granulomatous	2 [1.0]					1 [1.0]
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(9)
Lymph Node, Mesenteric	(9)	(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)	(9)

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Skin	(10)	(10)	(10)	(10)	(10)	(10)
Dermis, SOA, Inflammation, Chronic Active			1 [1.0]	8 [1.0]	10 [1.0]	10 [1.0]
Epidermis, SOA, Erosion						2 [1.5]
Epidermis, SOA, Inflammation, Suppurative				1 [1.0]	3 [1.0]	7 [1.1]
Epidermis, SOA, Ulcer						1 [1.0]
SOA, Hyperplasia			10 [1.3]	10 [1.3]	10 [1.5]	10 [2.0]
SOA, Parakeratosis			2 [1.0]	8 [1.3]	9 [1.1]	10 [1.8]
SOA, Sebaceous Gl, Hypertrophy					6 [1.5]	10 [2.0]
SOA, Ulcer				1 [1.0]		2 [2.0]
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)
Alveolar Epith, Inflammation, Chronic Active						1 [1.0]
Alveolus, Inflammation, Chronic Active	2 [1.0]					
Mineralization						1 [1.0]
Perivascular, Inflammation, Chronic Active	4 [2.0]					3 [2.0]
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular	1 [2.0]					2 [1.5]
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Mineralization	8 [1.3]					8 [1.0]

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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
Renal Tubule, Regeneration						1 [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

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