

TDMS No. 20307 - 03

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

Date Report Requested: 07/27/2011

Test Type: 90-DAY

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E
Super)

Time Report Requested: 12:19:40

Route: SKIN APPLICATION

CAS Number: 54464-57-2

First Dose M/F: 12/12/06 / 12/13/06

Species/Strain: RATS/F344/N Tac

Lab: MBA

F1_RD

C Number: C20307
Lock Date: 12/23/2009
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

Test Type: 90-DAY

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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Route: SKIN APPLICATION

CAS Number: 54464-57-2

First Dose M/F: 12/12/06 / 12/13/06

Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS 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	(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)	(10)	(10)
Inflammation, Chronic	1 [2.0]					
Oral Mucosa	(10)	(10)	(0)	(0)	(0)	(0)
Pancreas	(10)	(10)	(0)	(0)	(0)	(0)
Acinus, Atrophy		1 [2.0]				
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)
Cardiomyopathy	1 [1.0]	1 [1.0]				
Infiltration Cellular, Histiocyte, Focal						
Inflammation, Chronic	1 [2.0]					

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)

Test Type: 90-DAY

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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Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS MALE

	untreated	vehicle	6.25%	12.5%	25%	50%
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(10)	(0)	(0)	(0)	(0)
Adrenal Medulla	(10)	(10)	(0)	(0)	(0)	(0)
Parathyroid Gland	(10)	(10)	(0)	(0)	(0)	(0)
Pituitary Gland	(9)	(8)	(0)	(0)	(0)	(0)
Thyroid Gland	(10)	(10)	(0)	(0)	(0)	(0)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(10)	(0)	(0)	(0)	(0)
Preputial Gland	(9)	(8)	(0)	(0)	(0)	(0)
Inflammation, Chronic	2 [1.0]					
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)	(0)	(0)	(0)	(0)
Lymph Node	(0)	(0)	(0)	(0)	(0)	(0)
Mediastinal, Hyperplasia, Lymphoid, Diffuse						
Lymph Node, Mandibular	(10)	(10)	(0)	(0)	(0)	(0)
Lymph Node, Mesenteric	(10)	(10)	(0)	(0)	(0)	(0)
Infiltration Cellular, Histiocyte	1 [2.0]	1 [2.0]				
Spleen	(10)	(10)	(0)	(0)	(0)	(0)
Thymus	(10)	(10)	(0)	(0)	(0)	(0)

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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Lab: MBA

Fischer 344-Taconic RATS MALE

	untreated	vehicle	6.25%	12.5%	25%	50%
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(10)	(0)	(0)	(0)	(0)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Control, Hyperplasia			1 [1.0]			
Control, Inflammation			1 [1.0]			
Skin, Site Of Application	(10)	(10)	(10)	(10)	(10)	(10)
Hyperkeratosis			1 [1.0]	3 [1.0]	4 [1.0]	5 [1.0]
Hyperplasia			2 [1.0]	4 [1.0]	5 [1.0]	8 [1.5]
Inflammation						
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)
Inflammation, Neutrophil	1 [2.0]					
Lung	(10)	(10)	(0)	(0)	(0)	(0)
Hemorrhage	1 [3.0]					
Infiltration Cellular, Histiocyte						
Inflammation, Chronic	4 [2.3]	5 [2.6]				
Interstitial, Inflammation, Focal	2 [1.0]	1 [1.0]				
Nose	(10)	(10)	(0)	(0)	(0)	(0)
Trachea	(10)	(10)	(0)	(0)	(0)	(0)
SPECIAL SENSES SYSTEM						

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)

Test Type: 90-DAY

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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Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS MALE

	untreated	vehicle	6.25%	12.5%	25%	50%
Eye	(10)	(10)	(0)	(0)	(0)	(0)
Harderian Gland	(10)	(10)	(0)	(0)	(0)	(0)
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Nephropathy	10 [1.4]	8 [1.0]	9 [1.7]	10 [1.9]	10 [1.4]	10 [1.7]
Renal Tubule, Casts	3 [1.0]		1 [1.0]	1 [1.0]		1 [1.0]
Urinary Bladder	(10)	(10)	(0)	(0)	(0)	(0)

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Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS MALE 100%

Disposition Summary

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

ALIMENTARY SYSTEM

Esophagus	(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)
Inflammation, Chronic	
Oral Mucosa	(10)
Pancreas	(10)
Acinus, Atrophy	
Salivary Glands	(10)
Stomach, Forestomach	(10)
Stomach, Glandular	(10)
Tongue	(10)

CARDIOVASCULAR SYSTEM

Blood Vessel	(9)
Heart	(10)
Cardiomyopathy	1 [1.0]
Infiltration Cellular, Histiocyte, Focal	1 [1.0]
Inflammation, Chronic	

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Fischer 344-Taconic RATS MALE 100%

ENDOCRINE SYSTEM

Adrenal Cortex	(10)
Adrenal Medulla	(10)
Parathyroid Gland	(10)
Pituitary Gland	(9)
Thyroid Gland	(10)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(10)
Preputial Gland	(9)
Inflammation, Chronic	1 [1.0]
Prostate	(10)
Seminal Vesicle	(10)
Testes	(10)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)
Lymph Node	(1)
Mediastinal, Hyperplasia, Lymphoid, Diffuse	1 [3.0]
Lymph Node, Mandibular	(10)
Lymph Node, Mesenteric	(10)
Infiltration Cellular, Histiocyte	
Spleen	(10)
Thymus	(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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Lab: MBA

Fischer 344-Taconic RATS MALE

100%

INTEGUMENTARY SYSTEM

Mammary Gland	(10)
Skin	(10)
Control, Hyperplasia	
Control, Inflammation	
Skin, Site Of Application	(10)
Hyperkeratosis	8 [1.1]
Hyperplasia	10 [1.3]
Inflammation	1 [1.0]

MUSCULOSKELETAL SYSTEM

Bone	(10)
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NERVOUS SYSTEM

Brain	(10)
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RESPIRATORY SYSTEM

Larynx	(10)
Inflammation, Neutrophil	
Lung	(10)
Hemorrhage	
Infiltration Cellular, Histiocyte	1 [2.0]
Inflammation, Chronic	5 [2.2]
Interstitial, Inflammation, Focal	
Nose	(10)
Trachea	(10)

SPECIAL SENSES SYSTEM

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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Lab: MBA

Fischer 344-Taconic RATS MALE

100%

Eye	(10)
Harderian Gland	(10)

URINARY SYSTEM

Kidney	(10)
Nephropathy	10 [1.9]
Renal Tubule, Casts	
Urinary Bladder	(10)

*** END OF MALE ***

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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Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS 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)
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)
Inflammation, Chronic	6 [2.0]	5 [1.4]	7 [1.6]	9 [1.0]	5 [1.4]	5 [1.4]
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	(9)	(10)	(0)	(0)	(0)	(0)
Heart	(10)	(10)	(0)	(0)	(0)	(0)
Cardiomyopathy		1 [1.0]				

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

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

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Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS FEMALE

	untreated	vehicle	6.25%	12.5%	25%	50%
Adrenal Medulla	(10)	(10)	(0)	(0)	(0)	(0)
Parathyroid Gland	(9)	(10)	(0)	(0)	(0)	(0)
Pituitary Gland	(7)	(4)	(0)	(0)	(0)	(0)
Pars Distalis, Cyst, Multiple, Focal	1 [1.0]					
Thyroid Gland	(10)	(10)	(0)	(0)	(0)	(0)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(9)	(10)	(0)	(0)	(0)	(0)
Inflammation, Chronic		1 [1.0]				
Ovary	(10)	(10)	(0)	(0)	(0)	(0)
Uterus	(10)	(10)	(0)	(0)	(0)	(0)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(10)	(0)	(0)	(0)	(0)
Lymph Node	(0)	(1)	(0)	(0)	(0)	(0)
Iliac, Hyperplasia, Diffuse		1 [1.0]				
Lymph Node, Mandibular	(10)	(10)	(0)	(0)	(0)	(0)
Lymph Node, Mesenteric	(9)	(10)	(0)	(0)	(0)	(0)
Infiltration Cellular, Histiocyte	4 [1.3]	6 [1.7]				
Spleen	(10)	(10)	(0)	(0)	(0)	(0)
Thymus	(10)	(10)	(0)	(0)	(0)	(0)

INTEGUMENTARY SYSTEM

Mammary Gland	(8)	(10)	(0)	(0)	(0)	(0)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Skin, Site Of Application	(10)	(10)	(10)	(10)	(10)	(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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Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS FEMALE	untreated	vehicle	6.25%	12.5%	25%	50%
Hyperkeratosis				4 [1.0]	5 [1.4]	7 [1.3]
Hyperplasia			1 [1.0]	5 [1.0]	7 [1.3]	7 [1.4]
Dermis, Inflammation, Suppurative						
Hair Follicle, Necrosis						
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)
Infiltration Cellular, Histiocyte						
Inflammation, Chronic	2 [1.5]	3 [2.0]				
Mineralization		1 [1.0]				
Interstitial, Inflammation, Focal	3 [1.3]	1 [1.0]				
Nose	(10)	(10)	(0)	(0)	(0)	(0)
Trachea	(10)	(10)	(0)	(0)	(0)	(0)
SPECIAL SENSES SYSTEM						
Ear	(1)	(0)	(0)	(0)	(0)	(0)
Eye	(10)	(10)	(0)	(0)	(0)	(0)
Harderian Gland	(10)	(10)	(0)	(0)	(0)	(0)
Inflammation, Chronic	3 [1.3]	1 [1.0]				
URINARY SYSTEM						

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)

Test Type: 90-DAY

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Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS FEMALE

	untreated	vehicle	6.25%	12.5%	25%	50%
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic		2 [1.0]			1 [1.0]	
Mineralization		1 [1.0]			2 [1.0]	
Nephropathy	2 [1.0]	1 [1.0]				
Pelvis, Inflammation, Chronic						1 [2.0]
Urinary Bladder	(9)	(9)	(0)	(0)	(0)	(0)

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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Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS FEMALE 100%

Disposition Summary

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

ALIMENTARY SYSTEM

Esophagus	(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)
Inflammation, Chronic	5 [1.4]
Oral Mucosa	(10)
Pancreas	(10)
Salivary Glands	(10)
Stomach, Forestomach	(10)
Stomach, Glandular	(10)
Tongue	(10)

CARDIOVASCULAR SYSTEM

Blood Vessel	(10)
Heart	(10)
Cardiomyopathy	

ENDOCRINE SYSTEM

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

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First Dose M/F: 12/12/06 / 12/13/06

Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS FEMALE 100%

Adrenal Medulla	(10)
Parathyroid Gland	(10)
Pituitary Gland	(10)
Pars Distalis, Cyst, Multiple, Focal	
Thyroid Gland	(10)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(10)
Inflammation, Chronic	
Ovary	(10)
Uterus	(10)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)
Lymph Node	(0)
Iliac, Hyperplasia, Diffuse	
Lymph Node, Mandibular	(10)
Lymph Node, Mesenteric	(10)
Infiltration Cellular, Histiocyte	5 [2.2]
Spleen	(10)
Thymus	(10)

INTEGUMENTARY SYSTEM

Mammary Gland	(10)
Skin	(10)
Skin, Site Of Application	(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)

Test Type: 90-DAY

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super)

Time Report Requested: 12:19:40

Route: SKIN APPLICATION

CAS Number: 54464-57-2

First Dose M/F: 12/12/06 / 12/13/06

Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS FEMALE 100%

Hyperkeratosis	7 [1.9]
Hyperplasia	8 [1.9]
Dermis, Inflammation, Suppurative	1 [1.0]
Hair Follicle, Necrosis	1 [2.0]

MUSCULOSKELETAL SYSTEM

Bone	(10)
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NERVOUS SYSTEM

Brain	(10)
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RESPIRATORY SYSTEM

Larynx	(10)
Lung	(10)
Infiltration Cellular, Histiocyte	1 [1.0]
Inflammation, Chronic	1 [3.0]
Mineralization	
Interstitial, Inflammation, Focal	1 [1.0]
Nose	(10)
Trachea	(10)

SPECIAL SENSES SYSTEM

Ear	(1)
Eye	(10)
Harderian Gland	(10)
Inflammation, Chronic	3 [1.0]

URINARY SYSTEM

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)

Test Type: 90-DAY

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super)

Time Report Requested: 12:19:40

Route: SKIN APPLICATION

CAS Number: 54464-57-2

First Dose M/F: 12/12/06 / 12/13/06

Species/Strain: RATS/F344/N Tac

Lab: MBA

Fischer 344-Taconic RATS FEMALE 100%

Kidney	(10)
Inflammation, Chronic	
Mineralization	1 [2.0]
Nephropathy	
Pelvis, Inflammation, Chronic	
Urinary Bladder	(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)