

TDMS No. 20117 - 01

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS
ABRIDGED) (a)**

Date Report Requested: 06/30/2009

Test Type: 1-YEAR

All-trans-retinyl palmitate

Time Report Requested: 11:50:12

Route: SKIN APPLICATION

CAS Number: 79-81-2

First Dose M/F: 06/22/03 / NA

Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

C Number: C20117
Lock Date: 12/01/2008
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Male
TDMSE Version: 2.1.0

Test Type: 1-YEAR

All-trans-retinyl palmitate

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Route: SKIN APPLICATION

CAS Number: 79-81-2

First Dose M/F: 06/22/03 / NA

Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NO CREAMNO SSL-M	PH 7.0 NO SSL-M	2% RP NO SSL-M	.001% RANO SSL-M	NO CREAM6.75SSLM	PH 7.0 6.75SSLM
Disposition Summary						
Animals Initially in Study	34	36	36	36	36	36
Early Deaths						
Moribund Sacrifice	5	3	7	2	8	7
Natural Death	1	2	2		1	1
Survivors						
Moribund Sacrifice	1			1		
Terminal Sacrifice	27	29	3	20	25	1
Harvest		2	24	13	2	27
Animals Examined Microscopically	34	36			35	36

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None

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

Test Type: 1-YEAR

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First Dose M/F: 06/22/03 / NA

Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NO CREAMNO SSL-M	PH 7.0 NO SSL-M	2% RP NO SSL-M	.001% RANO SSL-M	NO CREAM6.75SSLM	PH 7.0 6.75SSLM
INTEGUMENTARY SYSTEM						
Skin, Control	(34)	(36)	(0)	(0)	(35)	(36)
Sarcoma					1 (3%)	
Squamous Cell Papilloma					1 (3%)	
Skin, Site Of Application	(34)	(36)	(0)	(0)	(35)	(36)
Basal Cell Adenoma						
Keratoacanthoma, One		3 (8%)				
Squamous Cell Carcinoma, One		1 (3%)			2 (6%)	7 (19%)
Squamous Cell Carcinoma, Two						2 (6%)
Squamous Cell Carcinoma, Three						
Squamous Cell Carcinoma, Four						
Squamous Cell Carcinoma, Five						
Squamous Cell Carcinoma, Greater Than Five						
Squamous Cell Carcinoma In Situ, One					1 (3%)	5 (14%)
Squamous Cell Carcinoma In Situ, Two						2 (6%)
Squamous Cell Carcinoma In Situ, Three						
Squamous Cell Carcinoma In Situ, Four						1 (3%)
Squamous Cell Carcinoma In Situ, Five						
Squamous Cell Carcinoma In Situ, Greater Than Five						
Squamous Cell Papilloma, One	1 (3%)	12 (33%)			4 (11%)	5 (14%)
Squamous Cell Papilloma, Two		4 (11%)				2 (6%)
Squamous Cell Papilloma, Three					1 (3%)	5 (14%)
Squamous Cell Papilloma, Four		1 (3%)				4 (11%)
Squamous Cell Papilloma, Five					1 (3%)	5 (14%)
Squamous Cell Papilloma, Greater Than Five						10 (28%)

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

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

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NO CREAMNO SSL-M	PH 7.0 NO SSL-M	2% RP NO SSL-M	.001% RANO SSL-M	NO CREAM6.75SSLM	PH 7.0 6.75SSLM
RESPIRATORY SYSTEM						
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						

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

Test Type: 1-YEAR

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	.1% RP 6.75SSLM	.5% RP 6.75SSLM	1% RP 6.75SSLM	2% RP 6.75SSLM	.001% RA6.75SSLM	NO CREAM13.7SSLM
Disposition Summary						
Animals Initially in Study	36	35	36	36	36	36
Early Deaths						
Moribund Sacrifice	3	3	1	4	1	
Natural Death				2		1
Survivors						
Moribund Sacrifice						
Terminal Sacrifice						
Harvest	33	32	35	30	35	35
Animals Examined Microscopically	36	35				36

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None

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

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	.1% RP 6.75SSLM	.5% RP 6.75SSLM	1% RP 6.75SSLM	2% RP 6.75SSLM	.001% RA6.75SSLM	NO CREAM13.7SSLM
INTEGUMENTARY SYSTEM						
Skin, Control	(36)	(35)	(0)	(0)	(0)	(36)
Sarcoma						
Squamous Cell Papilloma						
Skin, Site Of Application	(36)	(35)	(0)	(0)	(0)	(36)
Basal Cell Adenoma		1 (3%)				
Keratoacanthoma, One	1 (3%)					
Squamous Cell Carcinoma, One	5 (14%)	15 (43%)				13 (36%)
Squamous Cell Carcinoma, Two	3 (8%)	2 (6%)				7 (19%)
Squamous Cell Carcinoma, Three						6 (17%)
Squamous Cell Carcinoma, Four						
Squamous Cell Carcinoma, Five						1 (3%)
Squamous Cell Carcinoma, Greater Than Five						
Squamous Cell Carcinoma In Situ, One	7 (19%)	8 (23%)				7 (19%)
Squamous Cell Carcinoma In Situ, Two	3 (8%)	1 (3%)				3 (8%)
Squamous Cell Carcinoma In Situ, Three	1 (3%)					3 (8%)
Squamous Cell Carcinoma In Situ, Four						1 (3%)
Squamous Cell Carcinoma In Situ, Five						
Squamous Cell Carcinoma In Situ, Greater Than Five						
Squamous Cell Papilloma, One	4 (11%)	2 (6%)				12 (33%)
Squamous Cell Papilloma, Two	3 (8%)	1 (3%)				6 (17%)
Squamous Cell Papilloma, Three	1 (3%)	3 (9%)				1 (3%)
Squamous Cell Papilloma, Four	3 (8%)	6 (17%)				3 (8%)
Squamous Cell Papilloma, Five	3 (8%)	3 (9%)				
Squamous Cell Papilloma, Greater Than Five	18 (50%)	19 (54%)				1 (3%)

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

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

Test Type: 1-YEAR

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	.1% RP 6.75SSLM	.5% RP 6.75SSLM	1% RP 6.75SSLM	2% RP 6.75SSLM	.001% RA6.75SSLM	NO CREAM13.7SSLM
RESPIRATORY SYSTEM						
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						

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

Test Type: 1-YEAR

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	PH 7.0 13.7SSLM	.1% RP 13.7SSLM	.5% RP 13.7SSLM	1% RP 13.7SSLM	2% RP 13.7SSLM	.001% RA13.7SSLM
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Disposition Summary

Animals Initially in Study	36	36	36	36	36	36
Early Deaths						
Moribund Sacrifice	3	1		2	1	
Natural Death			1	1	1	
Survivors						
Moribund Sacrifice						
Terminal Sacrifice						
Harvest	33	35	35	33	34	36
Animals Examined Microscopically	36	36	36			

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None

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

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Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	PH 7.0 13.7SSLM	.1% RP 13.7SSLM	.5% RP 13.7SSLM	1% RP 13.7SSLM	2% RP 13.7SSLM	.001% RA13.7SSLM
INTEGUMENTARY SYSTEM						
Skin, Control	(36)	(36)	(36)	(0)	(0)	(0)
Sarcoma						
Squamous Cell Papilloma	1 (3%)					
Skin, Site Of Application	(36)	(36)	(36)	(0)	(0)	(0)
Basal Cell Adenoma						
Keratoacanthoma, One	1 (3%)	1 (3%)	1 (3%)			
Squamous Cell Carcinoma, One	10 (28%)	7 (19%)	7 (19%)			
Squamous Cell Carcinoma, Two	2 (6%)	7 (19%)	4 (11%)			
Squamous Cell Carcinoma, Three	6 (17%)	1 (3%)				
Squamous Cell Carcinoma, Four			1 (3%)			
Squamous Cell Carcinoma, Five	1 (3%)					
Squamous Cell Carcinoma, Greater Than Five						
Squamous Cell Carcinoma In Situ, One	12 (33%)	10 (28%)	13 (36%)			
Squamous Cell Carcinoma In Situ, Two	3 (8%)	3 (8%)	4 (11%)			
Squamous Cell Carcinoma In Situ, Three	2 (6%)	2 (6%)	1 (3%)			
Squamous Cell Carcinoma In Situ, Four	3 (8%)	1 (3%)				
Squamous Cell Carcinoma In Situ, Five	1 (3%)		1 (3%)			
Squamous Cell Carcinoma In Situ, Greater Than Five	1 (3%)	1 (3%)				
Squamous Cell Papilloma, One	3 (8%)	4 (11%)	3 (8%)			
Squamous Cell Papilloma, Two	8 (22%)	1 (3%)	1 (3%)			
Squamous Cell Papilloma, Three	3 (8%)	4 (11%)	3 (8%)			
Squamous Cell Papilloma, Four	2 (6%)	6 (17%)	6 (17%)			
Squamous Cell Papilloma, Five	2 (6%)	4 (11%)	2 (6%)			
Squamous Cell Papilloma, Greater Than Five	10 (28%)	15 (42%)	19 (53%)			

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

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

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Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	PH 7.0 13.7SSLM	.1% RP 13.7SSLM	.5% RP 13.7SSLM	1% RP 13.7SSLM	2% RP 13.7SSLM	.001% RA13.7SSLM
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RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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

Test Type: 1-YEAR

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE NOCREAMM20.55SSL 1% RP NO SSL-M

Disposition Summary

Animals Initially in Study	36	36
Early Deaths		
Moribund Sacrifice	1	7
Natural Death	1	1
Survivors		
Moribund Sacrifice		
Terminal Sacrifice		8
Harvest	34	20
Animals Examined Microscopically	36	

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None

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

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NOCREAMM20.55SSL	1% RP NO SSL-M
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INTEGUMENTARY SYSTEM

Skin, Control	(36)	(0)
Sarcoma		
Squamous Cell Papilloma		
Skin, Site Of Application	(36)	(0)
Basal Cell Adenoma		
Keratoacanthoma, One		
Squamous Cell Carcinoma, One	6 (17%)	
Squamous Cell Carcinoma, Two	8 (22%)	
Squamous Cell Carcinoma, Three	4 (11%)	
Squamous Cell Carcinoma, Four	5 (14%)	
Squamous Cell Carcinoma, Five	3 (8%)	
Squamous Cell Carcinoma, Greater Than Five	2 (6%)	
Squamous Cell Carcinoma In Situ, One	9 (25%)	
Squamous Cell Carcinoma In Situ, Two	3 (8%)	
Squamous Cell Carcinoma In Situ, Three	5 (14%)	
Squamous Cell Carcinoma In Situ, Four	1 (3%)	
Squamous Cell Carcinoma In Situ, Five	4 (11%)	
Squamous Cell Carcinoma In Situ, Greater Than Five	3 (8%)	
Squamous Cell Papilloma, One	7 (19%)	
Squamous Cell Papilloma, Two	3 (8%)	
Squamous Cell Papilloma, Three	7 (19%)	
Squamous Cell Papilloma, Four	2 (6%)	
Squamous Cell Papilloma, Five	1 (3%)	
Squamous Cell Papilloma, Greater Than Five	2 (6%)	

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE NOCREAMM20.55SSL 1% RP NO SSL-M

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

Test Type: 1-YEAR

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	NO CREAMNO SSL-M	PH 7.0 NO SSL-M	2% RP NO SSL-M	.001% RANO SSL-M	NO CREAM6.75SSLM	PH 7.0 6.75SSLM
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	1	18			8	32
Total Primary Neoplasms	1	21			11	48
Total Animals with Benign Neoplasms	1	18			6	31
Total Benign Neoplasms	1	20			7	31
Total Animals with Malignant Neoplasms		1			4	16
Total Malignant Neoplasms		1			4	17
Total Animals with Metastatic Neoplasms						
Total Metastatic Neoplasms						
Total Animals with Malignant Neoplasms Uncertain Primary Site						
Total Animals with Neoplasms Uncertain-Benign or Malignant						
Total Uncertain Neoplasms						

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

b - Primary tumors: all tumors except metastatic tumors

Test Type: 1-YEAR

All-trans-retinyl palmitate

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First Dose M/F: 06/22/03 / NA

Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	.1% RP 6.75SSLM	.5% RP 6.75SSLM	1% RP 6.75SSLM	2% RP 6.75SSLM	.001% RA6.75SSLM	NO CREAM13.7SSLM
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	32	35				36
Total Primary Neoplasms	52	61				64
Total Animals with Benign Neoplasms	32	34				23
Total Benign Neoplasms	33	35				23
Total Animals with Malignant Neoplasms	17	21				30
Total Malignant Neoplasms	19	26				41
Total Animals with Metastatic Neoplasms						
Total Metastatic Neoplasms						
Total Animals with Malignant Neoplasms Uncertain Primary Site						
Total Animals with Neoplasms Uncertain-Benign or Malignant						
Total Uncertain Neoplasms						

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

b - Primary tumors: all tumors except metastatic tumors

Test Type: 1-YEAR

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE MALE	PH 7.0 13.7SSLM	.1% RP 13.7SSLM	.5% RP 13.7SSLM	1% RP 13.7SSLM	2% RP 13.7SSLM	.001% RA13.7SSLM
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	33	35	36			
Total Primary Neoplasms	71	67	66			
Total Animals with Benign Neoplasms	29	34	34			
Total Benign Neoplasms	30	35	35			
Total Animals with Malignant Neoplasms	27	27	26			
Total Malignant Neoplasms	41	32	31			
Total Animals with Metastatic Neoplasms						
Total Metastatic Neoplasms						
Total Animals with Malignant Neoplasms Uncertain Primary Site						
Total Animals with Neoplasms Uncertain-Benign or Malignant						
Total Uncertain Neoplasms						

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

b - Primary tumors: all tumors except metastatic tumors

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

 SKH-1 HAIRLESS MICE (NCTR) MICE MALE NOCREAMM20.55SSL 1% RP NO SSL-M

Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	34
Total Primary Neoplasms	75
Total Animals with Benign Neoplasms	22
Total Benign Neoplasms	22
Total Animals with Malignant Neoplasms	31
Total Malignant Neoplasms	53
Total Animals with Metastatic Neoplasms	
Total Metastatic Neoplasms	
Total Animals with Malignant Neoplasms Uncertain Primary Site	
Total Animals with Neoplasms Uncertain-Benign or Malignant	
Total Uncertain Neoplasms	

 *** END OF MALE ***

*** END OF REPORT ***

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

b - Primary tumors: all tumors except metastatic tumors