

TDMS No. 20117 - 02

**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: 11:50:17

Route: SKIN APPLICATION

CAS Number: 79-81-2

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

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: Female

TDMSE Version: 2.1.0

Test Type: 1-YEAR

All-trans-retinyl palmitate

Time Report Requested: 11:50:17

Route: SKIN APPLICATION

CAS Number: 79-81-2

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

Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NO CREAMNO SSL-F	PH 7.0 NO SSL-F	2% RP NO SSL-F	.001% RANO SSL-F	NO CREAM6.75SSLF	PH 7.0 6.75SSLF
Disposition Summary						
Animals Initially in Study	36	36	36	36	36	36
Early Deaths						
Accidently Killed						
Moribund Sacrifice		3	16		2	
Natural Death	1		1	1	1	2
Survivors						
Moribund Sacrifice	1	3		1		
Terminal Sacrifice	34	28		29	30	24
Harvest		2	19	5	3	10
Animals Examined Microscopically	36	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 FEMALE	NO CREAMNO SSL-F	PH 7.0 NO SSL-F	2% RP NO SSL-F	.001% RANO SSL-F	NO CREAM6.75SSLF	PH 7.0 6.75SSLF
INTEGUMENTARY SYSTEM						
Skin, Control	(36)	(36)	(0)	(0)	(36)	(36)
Fibroma					1 (3%)	
Squamous Cell Papilloma		1 (3%)			2 (6%)	1 (3%)
Sebaceous Gland, Adenoma						
Skin, Site Of Application	(36)	(36)	(0)	(0)	(36)	(36)
Basal Cell Carcinoma						1 (3%)
Keratoacanthoma, One		1 (3%)				1 (3%)
Squamous Cell Carcinoma, One					1 (3%)	5 (14%)
Squamous Cell Carcinoma, Two						3 (8%)
Squamous Cell Carcinoma, Three						1 (3%)
Squamous Cell Carcinoma, Four						
Squamous Cell Carcinoma In Situ, One					1 (3%)	3 (8%)
Squamous Cell Carcinoma In Situ, Two					1 (3%)	2 (6%)
Squamous Cell Carcinoma In Situ, Three						1 (3%)
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%)	5 (14%)			11 (31%)	9 (25%)
Squamous Cell Papilloma, Two		2 (6%)				8 (22%)
Squamous Cell Papilloma, Three					2 (6%)	6 (17%)
Squamous Cell Papilloma, Four						1 (3%)
Squamous Cell Papilloma, Five						3 (8%)
Squamous Cell Papilloma, Greater Than Five						4 (11%)
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						

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 FEMALE	NO CREAMNO SSL-F	PH 7.0 NO SSL-F	2% RP NO SSL-F	.001% RANO SSL-F	NO CREAM6.75SSLF	PH 7.0 6.75SSLF
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						
SYSTEMIC LESIONS						
Multiple Organs	*(36)	*(36)			*(36)	*(36)
Lymphoma Malignant		1 (3%)				

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

* Number of animals with any tissue examined microscopically

Test Type: 1-YEAR

All-trans-retinyl palmitate

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	.1% RP 6.75SSLF	.5% RP 6.75SSLF	1% RP 6.75SSLF	2% RP 6.75SSLF	.001% RA6.75SSLF	NO CREAM13.7SSLF
Disposition Summary						
Animals Initially in Study	36	36	36	36	36	36
Early Deaths						
Accidently Killed						
Moribund Sacrifice	1	1	1	3	1	3
Natural Death	1		1		1	
Survivors						
Moribund Sacrifice						
Terminal Sacrifice	4				2	1
Harvest	30	35	34	33	32	32
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

* Number of animals with any tissue examined microscopically

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Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	.1% RP 6.75SSLF	.5% RP 6.75SSLF	1% RP 6.75SSLF	2% RP 6.75SSLF	.001% RA6.75SSLF	NO CREAM13.7SSLF
INTEGUMENTARY SYSTEM						
Skin, Control	(36)	(36)	(0)	(0)	(0)	(36)
Fibroma						
Squamous Cell Papilloma	1 (3%)	1 (3%)				
Sebaceous Gland, Adenoma						1 (3%)
Skin, Site Of Application	(36)	(36)	(0)	(0)	(0)	(36)
Basal Cell Carcinoma						1 (3%)
Keratoacanthoma, One						
Squamous Cell Carcinoma, One	10 (28%)	15 (42%)				12 (33%)
Squamous Cell Carcinoma, Two	2 (6%)	1 (3%)				8 (22%)
Squamous Cell Carcinoma, Three	1 (3%)					3 (8%)
Squamous Cell Carcinoma, Four	1 (3%)					1 (3%)
Squamous Cell Carcinoma In Situ, One	8 (22%)	9 (25%)				10 (28%)
Squamous Cell Carcinoma In Situ, Two						3 (8%)
Squamous Cell Carcinoma In Situ, Three	1 (3%)					2 (6%)
Squamous Cell Carcinoma In Situ, Four	1 (3%)					2 (6%)
Squamous Cell Carcinoma In Situ, Five						1 (3%)
Squamous Cell Carcinoma In Situ, Greater Than Five						
Squamous Cell Papilloma, One	6 (17%)	3 (8%)				13 (36%)
Squamous Cell Papilloma, Two	5 (14%)	7 (19%)				6 (17%)
Squamous Cell Papilloma, Three	4 (11%)	2 (6%)				2 (6%)
Squamous Cell Papilloma, Four	4 (11%)	10 (28%)				2 (6%)
Squamous Cell Papilloma, Five	5 (14%)	1 (3%)				4 (11%)
Squamous Cell Papilloma, Greater Than Five	7 (19%)	13 (36%)				2 (6%)

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

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

* Number of animals with any tissue examined microscopically

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	.1% RP 6.75SSLF	.5% RP 6.75SSLF	1% RP 6.75SSLF	2% RP 6.75SSLF	.001% RA6.75SSLF	NO CREAM13.7SSLF
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						
SYSTEMIC LESIONS						
Multiple Organs	*(36)	*(36)				*(36)
Lymphoma Malignant						

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

* Number of animals with any tissue examined microscopically

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	PH 7.0 13.7SSLF	.1% RP 13.7SSLF	.5% RP 13.7SSLF	1% RP 13.7SSLF	2% RP 13.7SSLF	.001% RA13.7SSLF
Disposition Summary						
Animals Initially in Study	36	36	36	36	36	36
Early Deaths						
Accidently Killed					1	
Moribund Sacrifice	3	2	2		4	1
Natural Death	1		2		1	
Survivors						
Moribund Sacrifice						
Terminal Sacrifice						
Harvest	32	34	32	36	30	35
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

* Number of animals with any tissue examined microscopically

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Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	PH 7.0 13.7SSLF	.1% RP 13.7SSLF	.5% RP 13.7SSLF	1% RP 13.7SSLF	2% RP 13.7SSLF	.001% RA13.7SSLF
INTEGUMENTARY SYSTEM						
Skin, Control	(36)	(36)	(36)	(0)	(0)	(0)
Fibroma						
Squamous Cell Papilloma	1 (3%)	2 (6%)				
Sebaceous Gland, Adenoma						
Skin, Site Of Application	(36)	(36)	(36)	(0)	(0)	(0)
Basal Cell Carcinoma						
Keratoacanthoma, One	1 (3%)					
Squamous Cell Carcinoma, One	12 (33%)	12 (33%)	9 (25%)			
Squamous Cell Carcinoma, Two	9 (25%)	9 (25%)	8 (22%)			
Squamous Cell Carcinoma, Three	3 (8%)	3 (8%)	5 (14%)			
Squamous Cell Carcinoma, Four	1 (3%)	5 (14%)	3 (8%)			
Squamous Cell Carcinoma In Situ, One	15 (42%)	8 (22%)	4 (11%)			
Squamous Cell Carcinoma In Situ, Two	2 (6%)	10 (28%)	2 (6%)			
Squamous Cell Carcinoma In Situ, Three	2 (6%)	1 (3%)	5 (14%)			
Squamous Cell Carcinoma In Situ, Four		2 (6%)				
Squamous Cell Carcinoma In Situ, Five		1 (3%)				
Squamous Cell Carcinoma In Situ, Greater Than Five		3 (8%)				
Squamous Cell Papilloma, One	5 (14%)	3 (8%)	1 (3%)			
Squamous Cell Papilloma, Two	12 (33%)	6 (17%)	3 (8%)			
Squamous Cell Papilloma, Three	3 (8%)	3 (8%)	3 (8%)			
Squamous Cell Papilloma, Four		4 (11%)	5 (14%)			
Squamous Cell Papilloma, Five	4 (11%)	3 (8%)	1 (3%)			
Squamous Cell Papilloma, Greater Than Five	7 (19%)	13 (36%)	15 (42%)			

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

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

* Number of animals with any tissue examined microscopically

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	PH 7.0 13.7SSLF	.1% RP 13.7SSLF	.5% RP 13.7SSLF	1% RP 13.7SSLF	2% RP 13.7SSLF	.001% RA13.7SSLF
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						
SYSTEMIC LESIONS						
Multiple Organs	*(36)	*(36)	*(36)			
Lymphoma Malignant						

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

* Number of animals with any tissue examined microscopically

Test Type: 1-YEAR

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE
FEMALE

NOCREAMF20.55SSL 1% RP NO SSL-F

Disposition Summary

Animals Initially in Study	36	36
Early Deaths		
Accidently Killed		
Moribund Sacrifice		5
Natural Death		1
Survivors		
Moribund Sacrifice		1
Terminal Sacrifice		9
Harvest	36	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

* Number of animals with any tissue examined microscopically

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAMF20.55SSL	1% RP NO SSL-F
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INTEGUMENTARY SYSTEM

Skin, Control	(36)	(0)
Fibroma		
Squamous Cell Papilloma		
Sebaceous Gland, Adenoma		
Skin, Site Of Application	(36)	(0)
Basal Cell Carcinoma		
Keratoacanthoma, One		
Squamous Cell Carcinoma, One	11 (31%)	
Squamous Cell Carcinoma, Two	8 (22%)	
Squamous Cell Carcinoma, Three	4 (11%)	
Squamous Cell Carcinoma, Four	3 (8%)	
Squamous Cell Carcinoma In Situ, One	9 (25%)	
Squamous Cell Carcinoma In Situ, Two	6 (17%)	
Squamous Cell Carcinoma In Situ, Three	4 (11%)	
Squamous Cell Carcinoma In Situ, Four	2 (6%)	
Squamous Cell Carcinoma In Situ, Five	1 (3%)	
Squamous Cell Carcinoma In Situ, Greater Than Five		
Squamous Cell Papilloma, One	9 (25%)	
Squamous Cell Papilloma, Two	4 (11%)	
Squamous Cell Papilloma, Three	4 (11%)	
Squamous Cell Papilloma, Four	1 (3%)	
Squamous Cell Papilloma, Five	1 (3%)	
Squamous Cell Papilloma, Greater Than Five	4 (11%)	

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

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

* Number of animals with any tissue examined microscopically

Test Type: 1-YEAR

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAMF20.55SSL	1% RP NO SSL-F
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None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

SYSTEMIC LESIONS

Multiple Organs Lymphoma Malignant		*(36)
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a - Number of animals examined microscopically at site and number of animals with lesion

* Number of animals with any tissue examined microscopically

Test Type: 1-YEAR

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NO CREAMNO SSL-F	PH 7.0 NO SSL-F	2% RP NO SSL-F	.001% RANO SSL-F	NO CREAM6.75SSLF	PH 7.0 6.75SSLF
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	1	10			17	33
Total Primary Neoplasms	1	10			19	50
Total Animals with Benign Neoplasms	1	9			14	31
Total Benign Neoplasms	1	9			16	33
Total Animals with Malignant Neoplasms		1			3	11
Total Malignant Neoplasms		1			3	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

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Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	.1% RP 6.75SSLF	.5% RP 6.75SSLF	1% RP 6.75SSLF	2% RP 6.75SSLF	.001% RA6.75SSLF	NO CREAM13.7SSLF
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	34	36				34
Total Primary Neoplasms	56	62				73
Total Animals with Benign Neoplasms	31	36				29
Total Benign Neoplasms	32	37				30
Total Animals with Malignant Neoplasms	19	21				31
Total Malignant Neoplasms	24	25				43
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 FEMALE	PH 7.0 13.7SSLF	.1% RP 13.7SSLF	.5% RP 13.7SSLF	1% RP 13.7SSLF	2% RP 13.7SSLF	.001% RA13.7SSLF
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	35	34	32			
Total Primary Neoplasms	77	88	64			
Total Animals with Benign Neoplasms	31	32	28			
Total Benign Neoplasms	33	34	28			
Total Animals with Malignant Neoplasms	32	34	28			
Total Malignant Neoplasms	44	54	36			
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
FEMALE

NOCREAMF20.55SSL 1% RP NO SSL-F

Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	33
Total Primary Neoplasms	71

Total Animals with Benign Neoplasms	23
Total Benign Neoplasms	23

Total Animals with Malignant Neoplasms	30
Total Malignant Neoplasms	48

Total Animals with Metastatic Neoplasms	
Total Metastatic Neoplasms	

Total Animals with Malignant Neoplasms Uncertain Primary Site	
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Total Animals with Neoplasms Uncertain-Benign or Malignant	
Total Uncertain Neoplasms	

*** 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