

**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

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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
<b>Disposition Summary</b>						
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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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
<b>INTEGUMENTARY SYSTEM</b>						
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%)
<b>MUSCULOSKELETAL SYSTEM</b>						
None						
<b>NERVOUS SYSTEM</b>						
None						
<b>RESPIRATORY SYSTEM</b>						

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

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

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
<b>Disposition Summary</b>						
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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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
<b>INTEGUMENTARY SYSTEM</b>						
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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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
<b>Disposition Summary</b>						
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
<b>INTEGUMENTARY SYSTEM</b>						
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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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

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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

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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%)	

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## 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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Lab: NCTR

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

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SPECIAL SENSES SYSTEM

None

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URINARY SYSTEM

None

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SYSTEMIC LESIONS

Multiple Organs Lymphoma Malignant		*(36)
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\* 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	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						

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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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Lab: NCTR

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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**

<b>Total Animals with Primary Neoplasms (b)</b>	34	36				34
<b>Total Primary Neoplasms</b>	56	62				73
<b>Total Animals with Benign Neoplasms</b>	31	36				29
<b>Total Benign Neoplasms</b>	32	37				30
<b>Total Animals with Malignant Neoplasms</b>	19	21				31
<b>Total Malignant Neoplasms</b>	24	25				43
<b>Total Animals with Metastatic Neoplasms</b>						
<b>Total Metastatic Neoplasms</b>						
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>						
<b>Total Animals with Neoplasms Uncertain-Benign or Malignant</b>						
<b>Total Uncertain Neoplasms</b>						

---

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

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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**

<b>Total Animals with Primary Neoplasms (b)</b>	35	34	32			
<b>Total Primary Neoplasms</b>	77	88	64			
<b>Total Animals with Benign Neoplasms</b>	31	32	28			
<b>Total Benign Neoplasms</b>	33	34	28			
<b>Total Animals with Malignant Neoplasms</b>	32	34	28			
<b>Total Malignant Neoplasms</b>	44	54	36			
<b>Total Animals with Metastatic Neoplasms</b>						
<b>Total Metastatic Neoplasms</b>						
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>						
<b>Total Animals with Neoplasms Uncertain-Benign or Malignant</b>						
<b>Total Uncertain Neoplasms</b>						

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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

NOCREAMF20.55SSL 1% RP NO SSL-F

### Tumor Summary for Females

<b>Total Animals with Primary Neoplasms (b)</b>	33
<b>Total Primary Neoplasms</b>	71

<b>Total Animals with Benign Neoplasms</b>	23
<b>Total Benign Neoplasms</b>	23

<b>Total Animals with Malignant Neoplasms</b>	30
<b>Total Malignant Neoplasms</b>	48

<b>Total Animals with Metastatic Neoplasms</b>	
<b>Total Metastatic Neoplasms</b>	

**Total Animals with Malignant Neoplasms Uncertain Primary Site**

<b>Total Animals with Neoplasms Uncertain-Benign or Malignant</b>	
<b>Total Uncertain Neoplasms</b>	

\*\*\* 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