

**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
<b>Disposition Summary</b>						
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

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
<b>INTEGUMENTARY SYSTEM</b>						
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

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
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

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

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
<b>Disposition Summary</b>						
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

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
<b>INTEGUMENTARY SYSTEM</b>						
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

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Route: SKIN APPLICATION

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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
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

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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			

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ALIMENTARY SYSTEM

None

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CARDIOVASCULAR SYSTEM

None

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ENDOCRINE SYSTEM

None

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GENERAL BODY SYSTEM

None

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GENITAL SYSTEM

None

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HEMATOPOIETIC SYSTEM

None

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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	PH 7.0 13.7SSLM	.1% RP 13.7SSLM	.5% RP 13.7SSLM	1% RP 13.7SSLM	2% RP 13.7SSLM	.001% RA13.7SSLM
<b>INTEGUMENTARY SYSTEM</b>						
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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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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First Dose M/F: 06/22/03 / NA

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

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 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%)	

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**MUSCULOSKELETAL SYSTEM**

None

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**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

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

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RESPIRATORY SYSTEM

None

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SPECIAL SENSES SYSTEM

None

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URINARY SYSTEM

None

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Test Type: 1-YEAR

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Lab: NCTR

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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**

<b>Total Animals with Primary Neoplasms (b)</b>	1	18			8	32
<b>Total Primary Neoplasms</b>	1	21			11	48
<b>Total Animals with Benign Neoplasms</b>	1	18			6	31
<b>Total Benign Neoplasms</b>	1	20			7	31
<b>Total Animals with Malignant Neoplasms</b>		1			4	16
<b>Total Malignant Neoplasms</b>		1			4	17
<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

All-trans-retinyl palmitate

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

Species/Strain: MICE/SKH-1/NCTR

Lab: NCTR

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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**

<b>Total Animals with Primary Neoplasms (b)</b>	32	35				36
<b>Total Primary Neoplasms</b>	52	61				64
<b>Total Animals with Benign Neoplasms</b>	32	34				23
<b>Total Benign Neoplasms</b>	33	35				23
<b>Total Animals with Malignant Neoplasms</b>	17	21				30
<b>Total Malignant Neoplasms</b>	19	26				41
<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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Lab: NCTR

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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**

<b>Total Animals with Primary Neoplasms (b)</b>	33	35	36			
<b>Total Primary Neoplasms</b>	71	67	66			
<b>Total Animals with Benign Neoplasms</b>	29	34	34			
<b>Total Benign Neoplasms</b>	30	35	35			
<b>Total Animals with Malignant Neoplasms</b>	27	27	26			
<b>Total Malignant Neoplasms</b>	41	32	31			
<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

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

### Tumor Summary for Males

<b>Total Animals with Primary Neoplasms (b)</b>	34
<b>Total Primary Neoplasms</b>	75
<b>Total Animals with Benign Neoplasms</b>	22
<b>Total Benign Neoplasms</b>	22
<b>Total Animals with Malignant Neoplasms</b>	31
<b>Total Malignant Neoplasms</b>	53
<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>	

\*\*\* 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