TDMS No. 20117 - 02

Route: SKIN APPLICATION

Species/Strain: MICE/SKH-1/NCTR

Test Type: 1-YEAR

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS

ABRIDGED) (a) All-trans-retinyl palmitate

CAS Number: 79-81-2

Date Report Requested: 06/30/2009

Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 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

OMS No. 20117 - 02 st Type: 1-YEAR oute: SKIN APPLICATION becies/Strain: MICE/SKH-1/NCTR	P05: INCIDENCE R	Date Report Requested: 06/30/2009 Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 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 6.75SSL
Disposition Summary						
Animals Initially in Study Early Deaths Accidently Killed	36	36	36	36	36	36
Moribund Sacrifice Natural Death	1	3	16 1	1	2 1	2
Survivors Moribund Sacrifice Terminal Sacrifice	1 34	3 28		1 29	30	24
Harvest Animals Examined Microscopically	36	2 36	19	5	3 36	10 36
ALIMENTARY SYSTEM						
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM None						
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM None						
HEMATOPOIETIC SYSTEM						
None						

None

MS No. 20117 - 02	P05: INCIDENCE R	ATES OF NEOPLASM	Date Report Req	uested: 06/30/2009		
st Type: 1-YEAR ute: SKIN APPLICATION ecies/Strain: MICE/SKH-1/NCTR		ABRIE All-trans-re CAS Num	Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 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 Squamous Cell Papilloma		1 (3%)			1 (3%) 2 (6%)	1 (3%)
Sebaceous Gland, Adenoma						
Skin, Site Of Application Basal Cell Carcinoma	(36)	(36)	(0)	(0)	(36)	(36) 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 Squamous Cell Carcinoma, Four						1 (3%)
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 Squamous Cell Carcinoma In Situ, Four						1 (3%) 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 Squamous Cell Papilloma, Five						1 (3%) 3 (8%)
Squamous Cell Papilloma, Greater Than						4 (11%)
Five						. ,

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

DMS No. 20117 - 02 P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)				Date Report Requested: 06/30/20		
est Type: 1-YEAR		Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03				
Route: SKIN APPLICATION Species/Strain: MICE/SKH-1/NCTR		CAS NUM	ı ber: 79-81-2		Lab: NCTR	NA / 00/22/03
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 Lymphoma Malignant	*(36)	*(36) 1 (3%)			*(36)	*(36)

MS No. 20117 - 02 st Type: 1-YEAR ute: SKIN APPLICATION ecies/Strain: MICE/SKH-1/NCTR	P05: INCIDENCE R	Date Report Requested: 06/30/2009 Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 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 CREAM13.7SSL
Disposition Summary						
Animals Initially in Study Early Deaths Accidently Killed	36	36	36	36	36	36
Moribund Sacrifice Natural Death Survivors	1 1	1	1 1	3	1 1	3
Moribund Sacrifice Terminal Sacrifice	4				2	1
Harvest Animals Examined Microscopically	30 36	35 36	34	33	32	32 36
ALIMENTARY SYSTEM						
None						
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
None						
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
None						
HEMATOPOIETIC SYSTEM						
None						

DMS No. 20117 - 02	P05: INCIDENCE R		Date Report Requested: 06/30/2009			
est Type: 1-YEAR oute: SKIN APPLICATION oecies/Strain: MICE/SKH-1/NCTR		ABRID All-trans-re CAS Num	Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 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	4 (00)	4 (00()				
Squamous Cell Papilloma	1 (3%)	1 (3%)				4 (00()
Sebaceous Gland, Adenoma	(26)	(26)	(0)	(0)	$\langle 0 \rangle$	1 (3%)
Skin, Site Of Application Basal Cell Carcinoma	(36)	(36)	(0)	(0)	(0)	(36) 1 (3%)
Keratoacanthoma, One						1 (376)
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%)	. (0,0)				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	0 (470()	0 (00()				40 (000()
Squamous Cell Papilloma, One	6 (17%) 5 (14%)	3 (8%)				13 (36%)
Squamous Cell Papilloma, Two	5 (14%)	7 (19%)				6 (17%)
Squamous Cell Papilloma, Three Squamous Cell Papilloma, Four	4 (11%) 4 (11%)	2 (6%) 10 (28%)				2 (6%) 2 (6%)
Squamous Cell Papilloma, Four Squamous Cell Papilloma, Five	4 (11%) 5 (14%)	1 (3%)				2 (6%) 4 (11%)
Squamous Cell Papilloma, Five Squamous Cell Papilloma, Greater Than	5 (14%) 7 (19%)	13 (36%)				2 (6%)
Five	1 (1970)	13 (30 %)				2 (070)

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

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

DMS No. 20117 - 02	P05: INCIDENCE R	Date Report Requested: 06/30/2009					
est Type: 1-YEAR		All-trans-re	IGED) (a) tinyl palmitate		Time Report Requested: 11:50:17		
oute: SKIN APPLICATION pecies/Strain: MICE/SKH-1/NCTR		CAS Num	ber: 79-81-2		First Dose M/F: Lab: NCTR	NA / 06/22/03	
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 Lymphoma Malignant	*(36)	*(36)				*(36)	

MS No. 20117 - 02 st Type: 1-YEAR pute: SKIN APPLICATION pecies/Strain: MICE/SKH-1/NCTR	P05: INCIDENCE R	Date Report Requested: 06/30/2009 Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 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 Early Deaths Accidently Killed	36	36	36	36	36 1	36
Moribund Sacrifice Natural Death Survivors Moribund Sacrifice	3 1	2	2 2		4 1	1
Terminal Sacrifice Harvest Animals Examined Microscopically	32 36	34 36	32 36	36	30	35
ALIMENTARY SYSTEM						
None						
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
None						
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
None						
HEMATOPOIETIC SYSTEM						
None						

TDMS No. 20117 - 02 P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (S)			(SYSTEMIC LESIONS	Date Report Requested: 06/30/2009 Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 Lab: NCTR		
Test Type: 1-YEAR Route: SKIN APPLICATION Species/Strain: MICE/SKH-1/NCTR	ABRIDGED) (a) All-trans-retinyl palmitate CAS Number: 79-81-2					
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	()	()	<i>i</i>		(-)	(-)
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 Squamous Cell Carcinoma In Situ,		1 (3%)				
Greater Than Five		3 (8%)				
Squamous Cell Papilloma, One	E (140/)	3 (8%)	1 (3%)			
Squamous Cell Papilloma, Two	5 (14%) 12 (33%)	6 (17%)				
Squamous Cell Papilloma, Two Squamous Cell Papilloma, Three	3 (8%)	3 (8%)	3 (8%) 3 (8%)			
Squamous Cell Papilloma, Four	3 (0 /0)	4 (11%)	5 (14%)			
Squamous Cell Papilloma, Five	4 (11%)	3 (8%)	1 (3%)			
Squamous Cell Papilloma, Five	7 (19%)	13 (36%)	15 (42%)			
Five	1 (13/0)		10 (42/0)			

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

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

DMS No. 20117 - 02	P05: INCIDENCE R	Date Report Requested: 06/30/200					
Fest Type: 1-YEAR			GED) (a) tinyl palmitate		Time Report Requested: 11:50:17		
Route: SKIN APPLICATION		CAS Num	ber: 79-81-2		First Dose M/F: N	A / 06/22/03	
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 Lymphoma Malignant	*(36)	*(36)	*(36)				

MS No. 20117 - 02 at Type: 1-YEAR ute: SKIN APPLICATION acies/Strain: MICE/SKH-1/NCTR	P05: INCIDENCE RA	TES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a) All-trans-retinyl palmitate CAS Number: 79-81-2	Date Report Requested: 06/30/20 Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 Lab: NCTR
SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAMF20.55SSL	1% RP NO SSL-F	
Disposition Summary			
Animals Initially in Study Early Deaths Accidently Killed Moribund Sacrifice	36	36 5	
Natural Death Survivors Moribund Sacrifice		1 1	
Terminal Sacrifice Harvest Animals Examined Microscopically	36 36	9 20	
ALIMENTARY SYSTEM			
None			
CARDIOVASCULAR SYSTEM			
None			
ENDOCRINE SYSTEM			
None			
GENERAL BODY SYSTEM			
None			
GENITAL SYSTEM			
None			
HEMATOPOIETIC SYSTEM			

TDMS No. 20117 - 02	P05: INCIDENCE RA	ATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)	Date Report Requested: 06/30/2009
Test Type: 1-YEAR Route: SKIN APPLICATION Species/Strain: MICE/SKH-1/NCTR		All-trans-retinyl palmitate CAS Number: 79-81-2	Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 Lab: NCTR
SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAMF20.55SSL	1% RP NO SSL-F	
INTEGUMENTARY SYSTEM			
Skin, Control Fibroma Squamous Cell Papilloma Sebaceous Gland, Adenoma	(36)	(0)	
Skin, Site Of Application Basal Cell Carcinoma Keratoacanthoma, One	(36)	(0)	
Squamous Cell Carcinoma, One Squamous Cell Carcinoma, Two Squamous Cell Carcinoma, Three Squamous Cell Carcinoma, Four	11 (31%) 8 (22%) 4 (11%) 2 (8%)		
Squamous Cell Carcinoma, Pour Squamous Cell Carcinoma In Situ, One Squamous Cell Carcinoma In Situ, Two Squamous Cell Carcinoma In Situ, Three	3 (8%) 9 (25%) 6 (17%) 4 (11%)		
Squamous Cell Carcinoma In Situ, Four Squamous Cell Carcinoma In Situ, Five Squamous Cell Carcinoma In Situ, Greater Than Five	2 (6%) 1 (3%)		
Squamous Cell Papilloma, One Squamous Cell Papilloma, Two Squamous Cell Papilloma, Three	9 (25%) 4 (11%) 4 (11%)		
Squamous Cell Papilloma, Four Squamous Cell Papilloma, Five Squamous Cell Papilloma, Greater Than Five	1 (3%) 1 (3%) 4 (11%)		

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

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

TDMS No. 20117 - 02 Test Type: 1-YEAR Route: SKIN APPLICATION Species/Strain: MICE/SKH-1/NCTR	P05: INCIDENCE RATES	S OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a) All-trans-retinyl palmitate CAS Number: 79-81-2	Date Report Requested: 06/30/2009 Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 Lab: NCTR	
SKH-1 HAIRLESS MICE (NCTR) MICE FEMALE	NOCREAMF20.55SSL 1	I% RP NO SSL-F		
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
None				
SYSTEMIC LESIONS				
Multiple Organs Lymphoma Malignant	*(36)			

DMS No. 20117 - 02	P05: INCIDENCE R	ATES OF NEOPLASM	Date Report Requested: 06/30/2009 Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03			
est Type: 1-YEAR Dute: SKIN APPLICATION		All-trans-re CAS Num				
becies/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 6.75SSL
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						

MS No. 20117 - 02	P05: INCIDENCE R	Date Report Requested: 06/30/2009				
st Type: 1-YEAR oute: SKIN APPLICATION ecies/Strain: MICE/SKH-1/NCTR		ABRID All-trans-re CAS Num	Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 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 CREAM13.7SSL
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						

TDMS No. 20117 - 02	P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a) All-trans-retinyl palmitate CAS Number: 79-81-2				Date Report Requested: 06/30/2009 Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03 Lab: NCTR	
Test Type: 1-YEAR Route: SKIN APPLICATION Species/Strain: MICE/SKH-1/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
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						

TDMS No. 20117 - 02	P05: INCIDENCE RA		Date Report Requested: 06/30/2009 Time Report Requested: 11:50:17 First Dose M/F: NA / 06/22/03		
Test Type: 1-YEAR		ABRIDGED) (a) All-trans-retinyl palmitate			
Route: SKIN APPLICATION		CAS Number: 79-81-2			
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					
Total Animals with Neoplasms Uncertain-Benign or Malignant					
Total Uncertain Neoplasms					
Neoplasms Uncertain Primary Site Total Animals with Neoplasms Uncertain-Benign or Malignant					

*** END OF REPORT ***